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IT DEPARTMENT

COMPUTER SYSTEM INITIAL RISK ASSESSMENT

Name of Item: Computer System

Protocol No.:.....

Functional Area: IT

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Instrument Name	Computer System
System ID.
System Used For	High Pressure Liquid Chromatography
Make	Waters
HPLC ID.
Application Software Type	Chromatographic <input checked="" type="checkbox"/> Non Chromatographic <input type="checkbox"/>
Application Software	Empower
Software Version	3.0
Make	Waters
System Type	New System <input type="checkbox"/> Existing system <input checked="" type="checkbox"/>
Location	Instrument Room



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RISK ASSESSMENT PRE APPROVAL PAGE:

Department	Name	Designation	Signature	Date
Prepared by: M/s.				
ENGINEERING				
Reviewed by: M/s.				
QUALITY ASSURANCE				
Reviewed by: M/s.				



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ENGINEERING				
Reviewed by: M/s.				
IT DEPARTMENT				
Reviewed by: M/s.				
QUALITY CONTROL				
Approved by: M/s.				
QUALITY ASSURANCE				



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A. COMMON RISK SCENARIOS:

S. No.	Risk Description	Impact of Possible Harm	Before Measures				Expected measures	Measures taken	After Measures			
			Likelihood	Severity	Detection	Overall Priority (RPN)			Likelihood	Severity	Detection	Overall Priority
1.0	RISK ON ACCOUNT OF UNAUTHORIZED SYSTEM ACCESS											
1.1	Unauthorized person tries to start/stop the system	Unauthorized persons may damage the system Untrained persons may disturb system that cause Quality system suffer.	8	7	9	504 High	<ul style="list-style-type: none"> System/Software should not start without user name & password Access control should be configured 					



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							<ul style="list-style-type: none"> • Only authorized personnel can access for operation and other activity 				
1.2	Access level are not configured	Untrained persons may access the restricted/ critical portion of the program	8	7	9	504 High	<ul style="list-style-type: none"> • Access level should be configured • System should generate an error message while invalid login attempted or not entering the main menu for Software or Operating System. • Different levels of access rights should be configured. 				



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1.3	Unauthorized person tries to access the secured system/command	Operation may be disturbed	8	7	9	504 High	<ul style="list-style-type: none"> System should not response when User trying to access the function which are accessible for Administration Level Users. 				
							<ul style="list-style-type: none"> System should allow functions only as per defined Desktop policy. 				
1.4	Unauthorized person tries to System settings and parameters	Proper functioning may be disturbed	8	7	9	504 High	<ul style="list-style-type: none"> System should not allow user to change system settings and parameters. 				



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1.5	Unauthorized person tries to restore/ change the System program	System may get damaged, loss of important data or process may occur	8	7	9	504 High	<ul style="list-style-type: none"> Access control should be clearly defined in desktop policy to prevent unauthorized access to System Program. 				
							<ul style="list-style-type: none"> Updating of the system program should be handled by qualified IT Personnel / vendor only 				
1.6	Roles and Privileges are not defined and are not Configured.	Anybody can access or modify data. Data Integrity may get compromised.	8	7	9	504 High	<ul style="list-style-type: none"> Roles and Privileges shall be clearly defined and Configured accordingly in the System Software. 				
1.7	User Security Policies are not configured for System Software	Unauthorized Access may create threat to sophisticated data.	8	7	9	504 High	<ul style="list-style-type: none"> User Security Policies shall be available, 				



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(Operating System and Application Software.						Configured accordingly.				
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S. No.	Risk Description	Impact of Possible Harm	Before Measures				Expected measures	Measures taken	After Measures			
			Likelihood	Severity	Detection	Overall Priority (RPN)			Likelihood	Severity	Detection	Overall Priority
2.0	RISK ON ACCOUNT NON AVAILABILITY OF STANDARD OPERATION PROCEDURES											



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S. No.	Risk Description	Impact of Possible Harm	Before Measures				Expected measures	Measures taken	After Measures			
			Likelihood	Severity	Detection	Overall Priority (RPN)			Likelihood	Severity	Detection	Overall Priority
2.1	User Operation SOP For Computer System and Applicable Software is not available or does not contain proper information.	In case relevant measures do not comply; user may make a wrong decision and incorrect operation.	5	8	9	360 High	<ul style="list-style-type: none"> System and Software operation SOP should be reviewed with all aspects and approved. All Authorized users should be trained properly. 					



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S. No.	Risk Description	Impact of Possible Harm	Before Measures				Expected measures	Measures taken	After Measures			
			Likelihood	Severity	Detection	Overall Priority (RPN)			Likelihood	Severity	Detection	Overall Priority
2.2	Change control SOP not available.	No control over process unauthorized change can be made with the system. In sufficient operation. Product quality gets affected.	5	8	9	360 High	<ul style="list-style-type: none"> System Change control SOP should be reviewed with all aspects and approved. 					
2.3	Preventive maintenance SOP not available.	System may damage/break down insufficient operation.	5	8	9	360 High	<ul style="list-style-type: none"> System Preventive maintenance SOP should be reviewed with all aspects and approved. 					



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S. No.	Risk Description	Impact of Possible Harm	Before Measures				Expected measures	Measures taken	After Measures			
			Likelihood	Severity	Detection	Overall Priority (RPN)			Likelihood	Severity	Detection	Overall Priority
2.4	Training SOP and records are not available.	System may damage. Insufficient operation. Product quality gets affected.	5	8	9	360 High	<ul style="list-style-type: none"> Training SOP & individual personnel training record should be available 					
2.5	Periodic review and performance monitoring SOP is not available	No control over process system may damage. Insufficient operation. Product quality gets affected.	5	8	9	360 High	<ul style="list-style-type: none"> Periodic review SOP should be available 					



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S. No.	Risk Description	Impact of Possible Harm	Before Measures				Expected measures	Measures taken	After Measures			
			Likelihood	Severity	Detection	Overall Priority (RPN)			Likelihood	Severity	Detection	Overall Priority
2.6	Procedure for Desktop policy is not available.	Any unauthorized person can change the current configuration of the system or data may be compromised.	5	8	9	360 High	<ul style="list-style-type: none"> SOP for Desktop Policy shall be available, reviewed and implemented. 					
2.7	Procedure for Backup and Data Restore is not available.	Disk space available with the system may get overloaded which adversely affects the system performance and stability.	5	8	9	360 High	<ul style="list-style-type: none"> Procedure for data backup and restore shall be available and implemented. 					



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			Likelihood	Severity	Detection	Overall Priority (RPN)			Likelihood	Severity	Detection	Overall Priority
2.8	Procedure for retention of record generated is not available.	No procedure for retention of records.	5	8	9	360 High	<ul style="list-style-type: none"> Procedure shall be available and implemented. 					
2.9	Procedure for disaster management is not available.	Data and information cannot be recovered during misshaping.	5	8	9	360 High	<ul style="list-style-type: none"> Procedure shall be available and implemented. 					



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			Likelihood	Severity	Detection	Overall Priority (RPN)			Likelihood	Severity	Detection	Overall Priority
2.10	Procedure For Incorrect User Operation and Vendor Management.	Intended or unintended deviations during user operation can occur and can remain un noticed or un handled.	5	8	9	360 High	<ul style="list-style-type: none"> • Procedure for Handling Deviation (Planned or Unplanned) Shall be Available Reviewed and Approved. 					
2.11	Procedure for Security Policy is not available.	Critical Information or Data Can Be Compromised.	5	8	9	360 High	<ul style="list-style-type: none"> • Procedure for Preparation and Proper implementation of Security Policies shall be available. 					



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S. No.	Risk Description	Impact of Possible Harm	Before Measures				Expected measures	Measures taken	After Measures			
			Likelihood	Severity	Detection	Overall Priority (RPN)			Likelihood	Severity	Detection	Overall Priority
3.0	RISK DUE TO IMPROPER TRAINING AND PROCEDURES											



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S. No.	Risk Description	Impact of Possible Harm	Before Measures				Expected measures	Measures taken	After Measures			
			Likelihood	Severity	Detection	Overall Priority (RPN)			Likelihood	Severity	Detection	Overall Priority
3.1	Untrained user tries to operate/maintenance of the system.	Loss of or damage to the system or product quality	5	8	9	360 High	<ul style="list-style-type: none"> Training records and SOP should be available 					
3.2	System maintenance not controlled	Loss of or damage to the system or product quality	5	8	9	360 High	<ul style="list-style-type: none"> Maintenance engineer should be available and should be adequately trained. 					



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S. No.	Risk Description	Impact of Possible Harm	Before Measures				Expected measures	Measures taken	After Measures			
			Likelihood	Severity	Detection	Overall Priority (RPN)			Likelihood	Severity	Detection	Overall Priority
							<ul style="list-style-type: none"> • System maintenance must be controlled through internal preventive maintenance schedule. • Periodic review of system should be done. 					



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			Likelihood	Severity	Detection	Overall Priority (RPN)			Likelihood	Severity	Detection	Overall Priority
4.0	RISK ON ACCOUNT NON AVAILABILITY OF SYSTEM RELATED DOCUMENT											
4.1	Operational and maintenance manual is not available	Machine maintenance get disturbed	5	8	9	360 High	<ul style="list-style-type: none"> Manual should be available 					



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			Likelihood	Severity	Detection	Overall Priority (RPN)			Likelihood	Severity	Detection	Overall Priority
4.2	Configuration document is not available	Machine maintenance get disturbed	5	8	9	360 High	<ul style="list-style-type: none"> Configuration document should be available 					



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B. FUNCTIONAL RISK ASSESSMENT:

Sr. No.	Risk Description	Impact of Possible Harm	Before Measures				Expected measures	Measures taken	After Measures			
			Likelihood	Severity	Detection	Overall Priority (RPN)			Likelihood	Severity	Detection	Overall Priority
1.0	RISK DUE TO IMPROPER CONFIGURATION OF THE SYSTEM											
1.1	Access control is not configured	System operation control may get lost and disturbed	5	8	9	360 High	<ul style="list-style-type: none"> Access control should be configured with rights of each level 					
1.2	Required software are not configured and updated.	Instrument operation control may get lost and disturbed	5	8	9	360 High	<ul style="list-style-type: none"> Set parameters should be configured with rights of each level 					



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Sr. No.	Risk Description	Impact of Possible Harm	Before Measures				Expected measures	Measures taken	After Measures			
			Likelihood	Severity	Detection	Overall Priority (RPN)			Likelihood	Severity	Detection	Overall Priority
1.3	Alarms are not Configured	Instrument operation control may get lost and disturbed	5	8	9	360 High	<ul style="list-style-type: none"> Alarm Should be configured with rights of each level 					



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			Likelihood	Severity	Detection	Overall Priority (RPN)			Likelihood	Severity	Detection	Overall Priority
2.0	RISK ON ACCOUNT OF ABNORMAL PROCESS CONDITIONS MAY OCCUR AT TIME OF SYSTEM OPERATION											
2.1	Restart button Pressed	System operation may get disturbed	6	8	9	432 High	<ul style="list-style-type: none"> Alarm message should be displayed on Screen. System should restart normally. 					



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			Likelihood	Severity	Detection	Overall Priority (RPN)			Likelihood	Severity	Detection	Overall Priority
3.0	RISK ON ACCOUNT OF GENERAL SYSTEM CONDITIONS OCCURRED											
3.1	Earthing is not provided to control System	Mother board may damage. System component may damage. Operator can injure from shock	5	8	9	360 High	<ul style="list-style-type: none"> Earthing should be provided. 					



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			Likelihood	Severity	Detection	Overall Priority (RPN)			Likelihood	Severity	Detection	Overall Priority
3.2	System is not operated within specified range of voltage.	System may damage Insufficient operation	5	8	9	360 High	<ul style="list-style-type: none"> Voltage should be as per requirement 					
3.3	System backup is not available	If data/ program of System gets lost/crashed, system, will not operate.	5	8	9	360 High	<ul style="list-style-type: none"> Program backup for System should be available 					



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S. No.	Risk Description	Impact of Possible Harm	Before Measures				Expected measures	Measures taken	After Measures			
			Likelihood	Severity	Detection	Overall Priority (RPN)			Likelihood	Severity	Detection	Overall Priority
4.0	RISK OCCURRED DURING PROCESS CONTROL SYSTEM FAILURE											
4.1	System control processor may fail during the operation.	Process control will be lost, which results data loss	3	8	10	240 High	<ul style="list-style-type: none"> System should be available with reliable and standard make 					



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			Likelihood	Severity	Detection	Overall Priority (RPN)			Likelihood	Severity	Detection	Overall Priority
4.2	Any of system component may get	Operation control may lose. Insufficient operation.	3	8	10	240 High	<ul style="list-style-type: none"> System shall be scanned regularly for faults. 					



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			Likelihood	Severity	Detection	Overall Priority (RPN)			Likelihood	Severity	Detection	Overall Priority
	faulty during operation						<ul style="list-style-type: none"> Spare Components shall be available. 					
5.0	RISK OCCURRED DURING CONTROL SYSTEM POWER FAILURE CONDITION.											
5.1	System power fails during operation.	Operation interrupted. System behaves abnormally	3	8	10	240 High	<ul style="list-style-type: none"> Supply of UPS shall be available for the system. Systems shall restarts normally 					
6.0	RISK OCCURRED DURING CONTROL SYSTEM COMMUNICATION FAILURE CONDITION											



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S. No.	Risk Description	Impact of Possible Harm	Before Measures				Expected measures	Measures taken	After Measures			
			Likelihood	Severity	Detection	Overall Priority (RPN)			Likelihood	Severity	Detection	Overall Priority
6.1	Communication fails between Server and System.	Operation interrupted. Configured parameters may be lost.	3	8	10	240 High	<ul style="list-style-type: none"> Alert should be displayed the communication fail alarm message. On condition of fail/re-establishment of the communication, All set parameter should remain unchanged 					



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7.0 CONCLUSION:

The details investigation of the entire risk scenario that may impact Computer system, performance and product quality has been performed. Impact analysis has been performed by applying the FMEA (Failure Mode Effect Analysis) tool of QRM (Quality Risk Management) approach for the current design control to the system. Following risk aspects has been considered to assure the related risk.

1. Risk on account of unauthorized system access.
2. Risk on account of non-availability SOP's.
3. Risk due to improper training and procedures.
4. Risk due to non-availability of operational manual.
5. Risk due to improper configuration of the system.
6. Risk on account of abnormal process conditions occurred at the time of system operation.
7. Risk on account of general system condition occurred.
8. Risk occurred during process control system failure.
9. Risk occurred during Computer system power failure condition.



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10. Risk occurred between Computer System communication failure conditions.

The risk assessment has been performed and risk priority number has been assigned as per level of Risk description which was evaluated likelihood and severity that is being implied to prevent the occurrence mentioned risk scenarios.

During the execution, the RPN (Risk priority number) for the contributing factors was high and after execution risk has been reduced to acceptable level by applying different expected control measure.



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RISK ASSESSMENT POST APPROVAL PAGE:

Department	Name	Designation	Signature	Date
Prepared by: M/s.				
ENGINEERING				
Reviewed by: M/s.				
QUALITY ASSURANCE				
Reviewed by: M/s.				
ENGINEERING				
Reviewed by: M/s.				
IT DEPARTMENT				



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Reviewed by: M/s.

QUALITY CONTROL

Approved by: M/s.

QUALITY ASSURANCE