



**RISK ASSESSMENT AND IMPACT ANALYSIS OF
PLC SYSTEM FOR
AUTOCOATER**

PROTOCOL No.:

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PLC SYSTEM FOR AUTOCOATER**

System Name	AUTOCOATER
System ID
Location	COATING
Effective Date	



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1.0.0 PRE APPROVAL SIGNATURES:

The signatures below indicate approval of this Risk assessment of PLC system of Autocoater indicates that it is ready for execution.

RISK ASSESSMENT PRE-APPROVAL

Function	Name	Department	Designation	Signature/Date
Prepared by		Engineering		
Reviewed by		Engineering		
Reviewed by		Production		
Reviewed by		Quality Assurance		

Final Approval:Final approval has been given by the following

Function	Name	Designation	Signature/Date
Approved by		Head Quality Assurance	



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2.0.0 GENERAL:

2.1.0 PURPOSE:

A principal purpose of this document is to identify and evaluate the risk factor of PLC system of Autocoater and also provides its mitigations. The purpose of the risk assessment is to minimize affect the safety, quality, reliability or durability of a product and to get maximum benefits of CGMP from PLC system of Autocoater .This document identifies the functions which may impact on patient safety, data integrity and product quality.

2.2.0 SCOPE:

The scope of this document is to identify the Risk of PLC Autocoater. Risk Assessment process has following points.

- Identify Risk
- Individual function risk scenario
- Identify and verify appropriate controls
- Mitigation for function risk scenario

2.3.0 BACKGROUND:

The “Autocoater ” is a new system purchase specifically for use at

2.4.0 REVISION HISTORY:

Version No.	Effective Date	Reason for Change
00		New Document



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2.5.0 REFERENCES:

The test and execution procedure within the scope of the Risk assessment document are consistence with the following reference.

<u>Guideline</u>	<u>Details</u>
GAMP-5	Good Automated Manufacturing Practices
21 CFR Part 210	Code of Federal Regulations, Current Good Manufacturing Practices in Manufacturing Processing, Packing.
21 CFR Part 211	Code of Federal Regulations, Current Good Manufacturing Practices for finished Pharmaceuticals.
EU GMP Annex-11	European Union Good Manufacturing Practices Annexure-11



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2.6.0 RESPONSIBILITY:

- Collect all manuals, electrical wiring diagram and documentary or any other data necessary for the preparation, execution of Risk Assessment document from
- Preparation and execution of Risk Assessment document.
- Initiate risk assessment study in coordination with Production, Quality Assurance and Engineering.
- Provide training to the persons, who present during execution, of this study.



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Engineering	Production	Quality Assurance
<p>3.0.0</p> <ul style="list-style-type: none"> ➤ Co-ordinate during execution of Risk Assessment. ➤ To provide utilities for Risk Assessment. ➤ To check the Risk Assessment document. 	<ul style="list-style-type: none"> ➤ Co-ordinate during execution of Risk Assessment activities. ➤ Provide personnel for facilitating the execution of Risk Assessment activity. ➤ Check that test requirements are completed. ➤ To check the Risk Assessment document. 	<ul style="list-style-type: none"> ➤ Co-ordinate during execution of Risk Assessment activities. ➤ To check and approve the Risk Assessment document.

RISK

ASSESSMENT:

- Risk is the combination of the probability of occurrence of harm & the severity of that harm. Risk assessment shall be done to determine the criticality of the system to the process (with respect to product efficacy or patient safety).
- Risk assessment together shall help to determine the strategy & priority in which each system should be addressed for remedial action. High criticality systems with poor compliance shall result in a high priority for remedial action, whereas, low criticality systems with poor compliance may fall below the threshold for remedial action.



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Risk Assessment Method





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- **Risk Severity (Impact or Significance):**

- Risk assessment requires not only the identification of the immediate effects of the risk but also the long term and widespread impact of those effects. These effects must take into account a wide variety of issues including impact on regulatory compliance. Impact on Patient safety, product quality and data integrity (or other harm) may be considered. A suggested method of representing this is as per as Low (L), Medium (M) or High (H).

- **Low:** Expected to have a minor negative impact. The damage would not be expected to have a long term detrimental effect.

- **Medium:** Expected to have a moderate impact. The impact could be expected to have short to medium term detrimental effects.

- **High:** Expected to have a very significant negative impact. The impact could be expected to have significant long-term effects and potentially catastrophic short-term effects.

- **Risk Classification (Risk Class):**

- Based on the Risk Likelihood & Severity of risk, identify the risk class. It may be mentioned as Class 1, Class 2 or Class 3 as per Table.

- **Probability of Detection (Detectability):**

- The purpose of this stage in the assessment process is to identify if the risk event is recognized or detected by other means in the system. Hence a Class 1 risk, if it has a high probability of detection may not pose such a serious threat because it can be recognized quickly and suitable corrective actions can be taken to mitigate its impact. Conversely, if the same fault has low probability of detection then one needs to seriously consider review of the design or the implementation of alternate procedures to avoid the event. It may be mentioned as Low (L), Medium (M) or High (H).

- **Low:** Detection of the fault condition is perceived to be unlikely.

- **Medium:** Detection of the fault condition is perceived to be reasonably likely.

- **High:** Detection of the fault condition is perceived to be highly likely.



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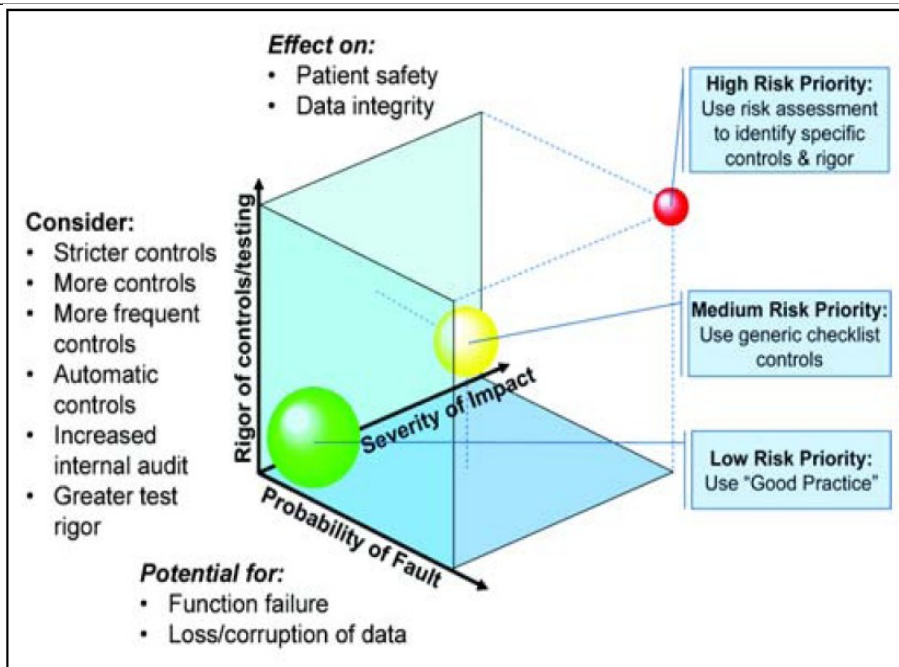
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• **Risk Priority:**

- o By combining the Risk Classification with the Probability of Detection, it is possible to prioritize, which determines how urgent and important it is to mitigate a particular risk.
- o Once these priorities have been determined the team can proceed to define and document the appropriate measure(s) to mitigate the adverse event that poses the risk. Risk Priority may be mentioned as High Priority, Medium Priority or Low Priority. Table below provides the guidance to arriving at the Risk Priority.
- o Risk assessment together shall help to determine the strategy & priority in which each system should be addressed for remedial action. High criticality systems with poor compliance shall result in a high priority for remedial action, whereas, low criticality systems with poor compliance may fall below the threshold for remedial action.

Relationship of Risk, Severity and Control





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• **Five step approach to risk management:**

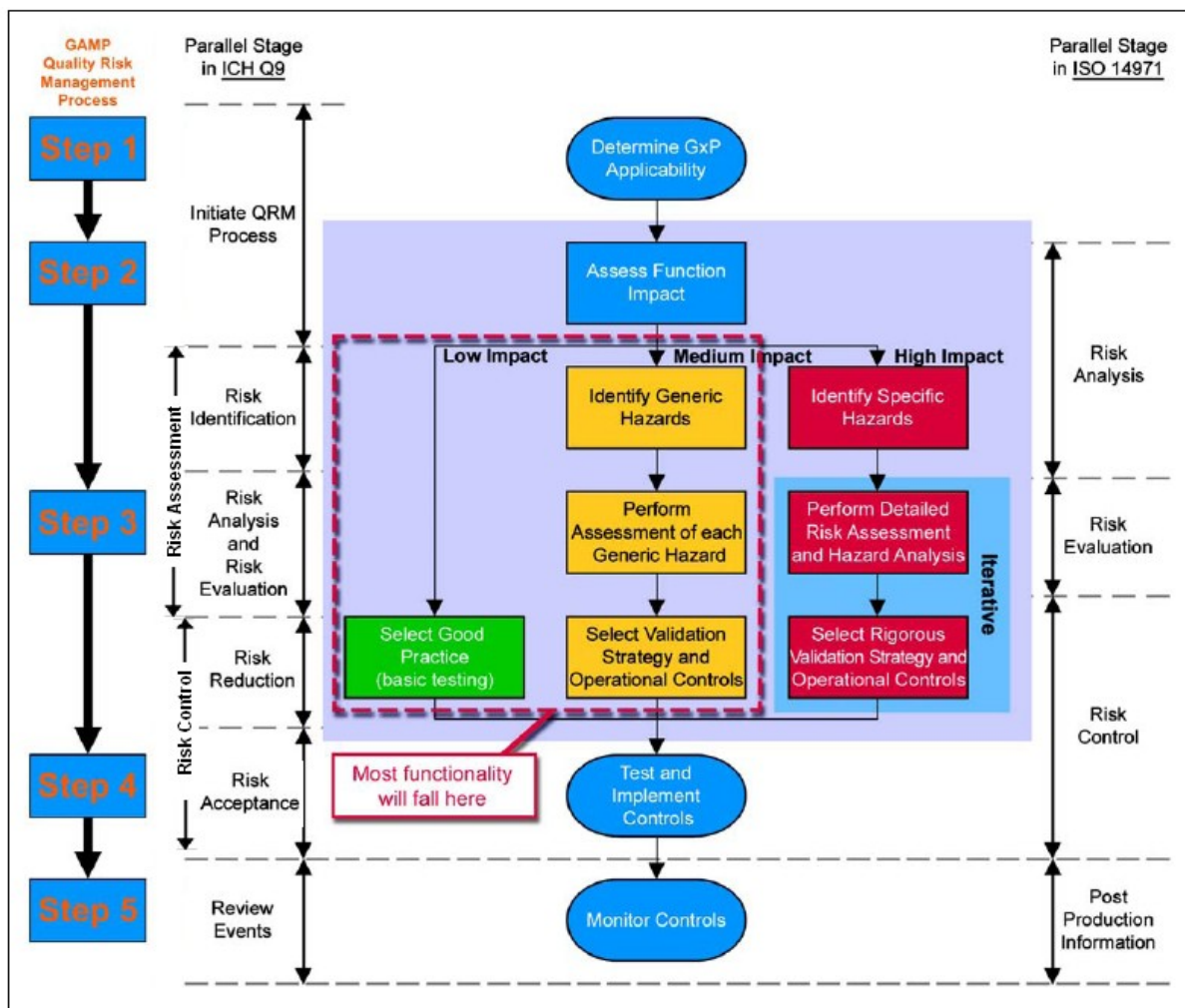
Step 1: Initial Assessment

Step 2: Identify functions with impact on patient safety, product quality & data integrity

Step 3: Perform functional risk assessments & identify controls

Step 4: Implement & verify appropriate testing & controls

Step 5: Review risks & monitor controls





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- Risk scenario & mitigation approaches are evaluated module wise.

- **Risk assessment should be performed considering the risk related to:**
 - Safety of product, personnel & environment
 - PLC system hardware (component & sub component) & software.
 - **Personnel:** All personnel should have appropriate qualifications, level of access and defined responsibility to carry out their assigned duties.
 - **Change and configuration Management:** Any changes to a PLC system including system configurations, hardware and software, should only be made in a controlled manner in accordance with a standard procedure.
 - **Periodic Evaluation:** PLC systems should be periodically evaluated to confirm that they remain in a valid state and are compliant with GMP.
 - **Security and authorization:** Physical and/or logical controls should be in place to restrict access to PLC system to authorized persons. Suitable methods of preventing unauthorized entry to the system may include the use of keys, passwords, restricted access to computer equipment and data storage areas.
 - **Business Continuity:** For the availability of PLC system of supporting critical processes, provisions should be made to ensure continuity of support for those processes in the event of a system break down. The time required to bring the alternative arrangements into use should be based on risk and appropriate for a particular system and the business process it supports. These arrangements should be adequately documented and tested.

- Interlocks are measures that are put in place to reduce risk to an acceptable level. Interlocks are aimed at:
 - Eliminating risk through process or system re-design: If any abnormality is observed during qualification the risk is mitigated through redesign the system.
 - Reducing risk by reducing the probability of a failure occurring.Reducing risk by increasing the in process detectability of failure (Emergency stop, limit switches, Sensors etc.).



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4.0.0 RISK ASSESSMENT

Risk assessment and control

Risk Area	Risk Identification	Likelihood	Severity	Risk Class	Detectability	Risk Priority	Measures and control (Risk mitigation)
Personal, GXP risk data integrity	Unauthorized person may try to operate system and manipulate the system data	Low	High	2	Medium	Medium	Logical (System should password protected) security should in place to restrict access to unauthorized persons.

Risk Assessment Post Mitigation

Likelihood	Severity	Risk Class	Detectability	Risk Priority	Residual Risk (Post Mitigation)	Risk Eliminated & Accepted/ Risk Reduced & Accepted
Low	High	2	High	Low	Negligible	

Remarks: _____

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Risk assessment and control

Risk Area	Risk Identification	Likelihood	Severity	Risk Class	Detectability	Risk Priority	Measures and control (Risk mitigation)
Equipment Risk	Unstable power supply may damage the PLC and HMI system	High	Medium	1	Low	High	Stable power supply (SMPS) should connect to equipment for prevention of PLC and HMI system.

Risk Assessment Post Mitigation

Likelihood	Severity	Risk Class	Detectability	Risk Priority	Residual Risk (Post Mitigation)	Risk Eliminated & Accepted/ Risk Reduced & Accepted
Low	Medium	Risk Class-3	High	Low	Negligible	

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Risk assessment and control

Risk Area	Risk Identification	Likelihood	Severity	Risk Class	Detectability	Risk Priority	Measures and control (Risk mitigation)
Business and GMP Risk	Untrained person may try to operate the system	Low	Medium	3	High	Low	Training should be available for equipment operation

Risk Assessment Post Mitigation

Likelihood	Severity	Risk Class	Detectability	Risk Priority	Residual Risk (Post Mitigation)	Risk Eliminated & Accepted/ Risk Reduced & Accepted
Low	Medium	3	High	Low	Negligible	

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Risk assessment and control

Risk Area	Risk Identification	Likelihood	Severity	Risk Class	Detectability	Risk Priority	Measures and control (Risk mitigation)
System and GMP Risk	Any Change or configuration in the system hardware/software may impact its functionality.	Medium	Medium	2	Medium	Medium	Any change to a PLC system should be done in accordance with a standard procedure. Major modifications/ changes shall be followed by re-validation.

Risk Assessment Post Mitigation

Likelihood	Severity	Risk Class	Detectability	Risk Priority	Residual Risk (Post Mitigation)	Risk Eliminated & Accepted/ Risk Reduced & Accepted
Low	Medium	3	High	Low	Negligible	

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Risk assessment and control

Risk Area	Risk Identification	Likelihood	Severity	Risk Class	Detectability	Risk Priority	Measures and control (Risk mitigation)
Process, personnel And equipment risk	Machine may not be stop in case of emergency Push Button Operated	Medium	High	1	High	Medium	Emergency stop alarm and Interlock should be available In the system.

Risk Assessment Post Mitigation

Likelihood	Severity	Risk Class	Detectability	Risk Priority	Residual Risk (Post Mitigation)	Risk Eliminated & Accepted/ Risk Reduced & Accepted
Low	High	2	High	Low	Negligible	

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Risk assessment and control

Risk Area	Risk Identification	Likelihood	Severity	Risk Class	Detectability	Risk Priority	Measures and control (Risk mitigation)
Process Risk	Main air pressure is less than the set air pressure	Low	High	Risk Class-2	Medium	Medium	Main Air pressure low Alarm and interlock should be available in the system.

Risk Assessment Post Mitigation

Likelihood	Severity	Risk Class	Detectability	Risk Priority	Residual Risk (Post Mitigation)	Risk Eliminated & Accepted/ Risk Reduced & Accepted
Low	High	2	High	Low	Negligible	

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Risk Area	Risk Identification	Likelihood	Severity	Risk Class	Detectability	Risk Priority	Measures and control (Risk mitigation)
Process Risk	Operator panel Air Pressure is less than the set air pressure	Low	Medium	Risk Class-3	High	Low	Operator Panel Air Pressure low Alarm and interlock should be available in the system.

Risk Assessment Post Mitigation

Likelihood	Severity	Risk Class	Detectability	Risk Priority	Residual Risk (Post Mitigation)	Risk Eliminated & Accepted/ Risk Reduced & Accepted
Low	Medium	3	High	Low	Negligible	

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Risk Area	Risk Identification	Likelihood	Severity	Risk Class	Detectability	Risk Priority	Measures and control (Risk mitigation)
Equipment & Process Risk	If Pan Motor VFD is ON and VFD ON Feedback is not received by PLC within 5 sec	Low	High	Risk Class-2	Medium	Medium	Pan Motor VFD fault Alarm and interlock Should be Available In the System.

Risk Assessment Post Mitigation

Likelihood	Severity	Risk Class	Detectability	Risk Priority	Residual Risk (Post Mitigation)	Risk Eliminated & Accepted/ Risk Reduced & Accepted
Low	High	2	High	Low	Negligible	

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Risk assessment and control

Risk	Risk			Risk		Risk	Measures
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Area	Identification	Likelihood	Severity	Class	Detectability	Priority	and control (Risk mitigation)
Equipment, Process Risk	If Exhaust air Blower VFD is ON and VFD ON Feedback is not received by PLC within 5 sec	Medium	Low	Risk Class-3	High	Low	Exhaust Air Blower VFD Fault Alarm and interlock should be available in the system.

Risk Assessment Post Mitigation

Likelihood	Severity	Risk Class	Detectability	Risk Priority	Residual Risk (Post Mitigation)	Risk Eliminated & Accepted/ Risk Reduced & Accepted
Low	Low	3	High	Low	Negligible	

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Risk Area	Risk Identification	Likelihood	Severity	Risk Class	Detectability	Risk Priority	Measures and control (Risk mitigation)
Equipment Risk	If Supply Air Blower VFD is ON and VFD ON feedback is not received by PLC within 5 sec	Low	Medium	Risk Class-3	Medium	Low	Supply Air Blower VFD fault Alarm and interlock should be available in system.

Risk Assessment Post Mitigation

Likelihood	Severity	Risk Class	Detectability	Risk Priority	Residual Risk (Post Mitigation)	Risk Eliminated & Accepted/ Risk Reduced & Accepted
Low	Medium	3	High	Low	Negligible	

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Risk Area	Risk Identification	Likelihood	Severity	Risk Class	Detectability	Risk Priority	Measures and control (Risk mitigation)
Equipment & Process Risk	If Atomisation air pressure is less than set value	Medium	Medium	Risk Class-2	High	Low	Atomising air pressure low alarm and interlock should be available in system

Risk Assessment Post Mitigation

Likelihood	Severity	Risk Class	Detectability	Risk Priority	Residual Risk (Post Mitigation)	Risk Eliminated & Accepted/ Risk Reduced & Accepted
Low	Medium	3	High	Low	Negligible	

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Risk assessment and control

Risk Area	Risk Identification	Likelihood	Severity	Risk Class	Detectability	Risk Priority	Measures and control (Risk mitigation)
Equipment, Process Risk	If DP across cabinet and HEPA filter Equals/exceeds the DP across cabinet and HEPA filter High set point	Medium	Medium	Risk Class-2	High	Low	DP Across Cabinet is high and DP Across HEPA Filter is High alarm and interlock should be available in system

Risk Assessment Post Mitigation

Likelihood	Severity	Risk Class	Detectability	Risk Priority	Residual Risk (Post Mitigation)	Risk Eliminated & Accepted/ Risk Reduced & Accepted
Low	Medium	3	High	Low	Negligible	

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Risk Area	Risk Identification	Likelihood	Severity	Risk Class	Detectability	Risk Priority	Measures and control (Risk mitigation)
Process Risk	If DP Across Secondary filter equals/exceeds the DP across secondary filter high set point	Low	High	Risk Class-2	High	Low	DP across secondary filter is high alarm and interlock should be available in system.

Risk Assessment Post Mitigation

Likelihood	Severity	Risk Class	Detectability	Risk Priority	Residual Risk (Post Mitigation)	Risk Eliminated & Accepted/ Risk Reduced & Accepted
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Risk Area	Risk Identification	Likelihood	Severity	Risk Class	Detectability	Risk Priority	Measures and control (Risk mitigation)
Product & Process Risk	If inlet temperature equals/exceeds the inlet temperature high set point.	Medium	High	Risk Class-1	High	Medium	Inlet Temperature high alarm and interlock should be available in system

Risk Assessment Post Mitigation

Likelihood	Severity	Risk Class	Detectability	Risk Priority	Residual Risk (Post Mitigation)	Risk Eliminated & Accepted/ Risk Reduced & Accepted
Low	High	2	High	Low	Negligible	

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Risk Area	Risk Identification	Likelihood	Severity	Risk Class	Detectability	Risk Priority	Measures and control (Risk mitigation)
Product & Process Risk	If exhaust temperature equals/exceeds the exhaust temperature high set point.	Medium	High	Risk Class-1	High	Medium	Exhaust temperature is high alarm and interlock should be available in the system.

Risk Assessment Post Mitigation

Likelihood	Severity	Risk Class	Detectability	Risk Priority	Residual Risk (Post Mitigation)	Risk Eliminated & Accepted/ Risk Reduced & Accepted
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Risk Area	Risk Identification	Likelihood	Severity	Risk Class	Detectability	Risk Priority	Measures and control (Risk mitigation)
Product Risk	If RH equals/exceeds the RH high set point	Low	Medium	Risk Class-3	Medium	Low	RH is high alarm and interlock should be available in the system.

Risk Assessment Post Mitigation

Likelihood	Severity	Risk Class	Detectability	Risk Priority	Residual Risk (Post Mitigation)	Risk Eliminated & Accepted/ Risk Reduced & Accepted
Low	Medium	3	High	Low	Negligible	

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Risk Area	Risk Identification	Likelihood	Severity	Risk Class	Detectability	Risk Priority	Measures and control (Risk mitigation)
Process Risk	If person is trying to switch ON auto/manual/maintenance mode & sel. Switch is not in production position.	Low	High	Risk Class-2	High	Low	Wash/prod sel. Switch is not in production position alarm and interlock should be available in the system.

Risk Assessment Post Mitigation

Likelihood	Severity	Risk Class	Detectability	Risk Priority	Residual Risk (Post Mitigation)	Risk Eliminated & Accepted/ Risk Reduced & Accepted
Low	High	2	High	Low	Negligible	

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Risk Area	Risk Identification	Likelihood	Severity	Risk Class	Detectability	Risk Priority	Measures and control (Risk mitigation)
Process Risk	If person is trying to switch ON wash mode & sel. Switch is not in wash position	Low	High	Risk Class-2	High	Low	Wash/prod sel. Switch is not in wash position alarm and interlock should be available in the system.

Risk Assessment Post Mitigation

Likelihood	Severity	Risk Class	Detectability	Risk Priority	Residual Risk (Post Mitigation)	Risk Eliminated & Accepted/ Risk Reduced & Accepted
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Risk Area	Risk Identification	Likelihood	Severity	Risk Class	Detectability	Risk Priority	Measures and control (Risk mitigation)
Process Risk	If WIP water pump is ON and its ON feedback is not received within 5 sec.	Low	High	Risk Class-2	High	Low	WIP Water Pump not ON alarm and interlock should be available in the system.

Risk Assessment Post Mitigation

Likelihood	Severity	Risk Class	Detectability	Risk Priority	Residual Risk (Post Mitigation)	Risk Eliminated & Accepted/ Risk Reduced & Accepted
Low	high	2	High	Low	Negligible	

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Risk Area	Risk Identification	Likelihood	Severity	Risk Class	Detectability	Risk Priority	Measures and control (Risk mitigation)
Process and Equipment Risk	If WIP water pump Overload feedback is recieved	Low	High	Risk Class-2	High	Low	WIP water pump Overload alarm and interlock should be available in the system.

Risk Assessment Post Mitigation

Likelihood	Severity	Risk Class	Detectability	Risk Priority	Residual Risk (Post Mitigation)	Risk Eliminated & Accepted/ Risk Reduced & Accepted
Low	high	2	High	Low	Negligible	

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Risk assessment and control

Risk Area	Risk Identification	Likelihood	Severity	Risk Class	Detectability	Risk Priority	Measures and control (Risk mitigation)
Product & Process Risk	If scrubber pump is ON and scrubber pump ON feedback is not received by PLC within 5 sec	Medium	High	Risk Class-1	High	Medium	Scrubber pump not ON alarm and interlock should be available in the system.

Risk Assessment Post Mitigation

Likelihood	Severity	Risk Class	Detectability	Risk Priority	Residual Risk (Post Mitigation)	Risk Eliminated & Accepted/ Risk Reduced & Accepted
Low	high	2	High	Low	Negligible	

Remarks: _____

Done By Sign / Date: _____ Verified By (QA) Sign / Date: _____



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Risk assessment and control

Risk Area	Risk Identification	Likelihood	Severity	Risk Class	Detectability	Risk Priority	Measures and control (Risk mitigation)
Equipment, Product & Process Risk	If Scrubber pump Overload feedback is received.	Medium	High	Risk Class-1	High	Medium	Scrubber pump Overload alarm and interlock should be available in the system.

Risk Assessment Post Mitigation

Likelihood	Severity	Risk Class	Detectability	Risk Priority	Residual Risk (Post Mitigation)	Risk Eliminated & Accepted/ Risk Reduced & Accepted
Low	high	2	High	Low	Negligible	

Remarks: _____

Done By Sign / Date: _____ **Verified By (QA) Sign / Date:** _____



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Risk assessment and control

Risk Area	Risk Identification	Likelihood	Severity	Risk Class	Detectability	Risk Priority	Measures and control (Risk mitigation)
Process Risk	If exhaust temp. Less than or equal to exhaust temp. Low set point.	Medium	High	Risk Class-1	High	Medium	Exhaust temperature is Low alarm and interlock should be available in the system.

Risk Assessment Post Mitigation

Likelihood	Severity	Risk Class	Detectability	Risk Priority	Residual Risk (Post Mitigation)	Risk Eliminated & Accepted/ Risk Reduced & Accepted
Low	high	2	High	Low	Negligible	

Remarks: _____

Done By Sign / Date: _____ Verified By (QA) Sign / Date: _____



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5.0.0 SUMMARY REPORT

Function	Name	Department	Sign. & Date
Done by		Validation Engineering	
Verified by		QA	



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6.0.0 LIST OF ABBREVIATIONS

<u>Acronym</u>	<u>Description</u>
CGMP	□ C urrent G ood M anufacturing P ractices
GAMP	□ G ood A utomated M anufacturing P ractices
GMP	□ G ood M anufacturing P ractices
ID	□ I dentification N umber
IO	□ I nput O utput
IQ	□ I nstallation Q ualification
PLC	□ P rogrammable L ogic C ontroller
CFR	□ C ode of F ederal R egulation
HMI	□ H uman M achine I nterface
RA	□ R isk A ssessment
M/C	□ M achine



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7.0.0 POST APPROVAL SIGNATURES

This is specific Risk Assessment of the PLC system of Autocoater . This Document is Checked and approved by the following.

RISK ASSESSMENT POST APPROVAL

Function	Name	Department	Designation	Signature/Date
Checked by		Engineering		
Reviewed by		Engineering		
Reviewed by		Production		
Reviewed by		Quality Assurance		

Final Approval: Final approval has been given by the following

Function	Name	Designation	Signature/Date
Approved by		Head Quality Assurance	