RISK ASSESSMENT STUDY

(FMEA ANALYSIS)

FOR

REPLACEMENT OF PLC IN AUTOCOATER MACHINE

Document No.:

Effective From/Approval Date: ……

Risk Review Due on:……

Remarks:

Risk assessment is prepared based on Change control. The changes for replacement of PLC in auto-coater machine shall be done through change control

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1.0 Quality Risk Management Team:

Following team members were involved during risk identification, assessment & brain storming session.

Team nomination was done by the head of department.

S.No.	Team Member	Department	Designation	Sign / Date
HOD Approval				
Name		**Department**	**Designation**	**Sign / Date**

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2.0 Introduction:

The facility is producing various ranges of tablets capsules and oral liquid with the help of require utility & equipment's.

3.0 Objective:

The objective of this protocol is to perform the Quality Risk assessment study against reported breakdown as per request. In view of proposal for replacement of PLC in auto coater machine, risk assessment study shall be performed.

4.0 Scope:

The scope of this document is to offer a systematic approach to quality risk management. It serves as a foundation or resource document that is independent of, yet supports other ICH Quality documents and complements existing quality practices, requirements, standards, and guidelines within the manufacturing facility.

The scope of this assessment is limited to identify evaluate & provide controlling measure (if required) against the risk associated for replacement of PLC in auto-coater m/c having equipment ID as well as evaluates the mitigation & acceptance the risk associated with it.

5.0 Risk Assessment Approach:

- The quality risk assessment has been planned for evaluation on the basis of failure mode effect analysis (FMEA) tool.
- The evaluation of the risk shall be based on scientific knowledge and ultimately linked to safety of the patient.
- Various risks associated / anticipated shall be for replacement of PLC in auto-coater machine.
- Risk over the quality of products manufactured in the equipment shall be identified, analyzed and evaluated. Control measures shall be evaluated and risk shall be categorized based on calculated risk priority number.
- Action recommendations shall be given (if required) for mitigation and acceptance of risk.
- Acceptance of the risk with its mitigating measures shall be decided and endorsed based on the risk assessment carried out.
- The control mechanism and the risk communication shall be enforced/verified in the operating documentation.

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6.0 Responsibility:

Engineering Department is responsible for preparation and review of quality risk assessment procedure and its execution.

Production Department is responsible for review of quality risk assessment procedure and its execution.

IT Department is responsible for review of quality risk assessment procedure and its execution.

Quality Assurance is responsible for review of quality risk assessment and its execution.

Head Quality Assurance/designee is responsible for approval adequacy of quality risk assessment and approves the final decision taken after recommended action plan (if any).

Head Operations is responsible for approval adequacy of quality risk assessment.

7.0 Reference Documents:

The relevant SOP's & Document for monitoring, control are listed below:

- SOP - Quality Risk management.
- SOP - Procedure for handling Breakdown of equipment's.
- SOP - Calibration Policy
- SOP - Change management system
- SOP- Qualification of Equipment, Facility, Utilities and System
- SOP- Computerized system validation.

8.0 Background:

On dated ……. breakdown intimation request intimation no. received for PLC to SCADA communication failed observed in IPC of Auto-coater machine having equipment ID. As per utility evaluation it was observed that PLC found faulty. So, as per recommendation PLC need to be replaced with new one. It is proposed to change the faulty PLC of auto-coater machine having equipment with spare PLC.

Risk assessment study for replacement of PLC of auto-coater machine having equipment ID, in line with the guidance of the Risk Management of Macleod's and ICH Q9

9.0 Risk Ranking Parameters:

9.1 Rating Parameters for Severity:

Effect	Scale	Assessment of Severity of Impact (Based on the anticipated negative impact & detrimental effect)
No effect	1	No impact to product quality and process robustness
Very slight	2	Very slight effect on product and process performance. The customer may notice non-vital fault. Customer is not annoyed or impacted.
Slight	3	Slight effect on performance. Non-vital fault notice most of the time. Customer is slightly annoyed.
Minor	4	Minor effect on product quality and process performance. Fault does not require repair or rectification. Non-vital fault or deficiency always noticed. Customer experiences minor nuisance.
Moderate	5	Performance moderately affected. Fault requires repair. Customer experiences some dissatisfaction.
Significant	6	Product or Performance hindered but usable /operable and safe. Non-vital part inoperable. Customer experiences discomfort.
Major	7	Product or performance severely affected but functional and safe. Customer dissatisfied.
Extreme	8	Item inoperable but safe. Customer very dissatisfied.
Serious	9	Potential hazardous effect. Able to stop without mishap. Regulatory compliance in jeopardy.
Hazardous	10	Occurrence without warning. Safety related. Regulatory non-compliance.

9.2 Rating parameters for Occurrence:

Occurrence	Scale	Parameter
Almost never	1	Almost impossible probability of occurrence. A failure, which has never been encountered but may be possible theoretically (1 in 1,1500,000).
Remote	2	Remote, rare number of historical failure (1 in 1,50,000).
Very slight	3	Very few failures likely (1 in 15,000)
Slight	4	Few failures likely (1 in 2,000)
Low	5	Occasional number of failures likely (1 in 400)
Medium	6	Medium number of failures likely (1 in 80)
Moderately High	7	Moderately high number of failures likely (1 in 20)
High	8	High number of failures likely (1 in 8)
Very High	9	Very high number of failures likely (1 in 3)
Almost certain	10	Failure almost certain (≥ 1 in 2)

9.3 Rating parameters for Detection Control:

Detection	Scale	Parameter
Almost certain	1	Almost certain that the design control will detect potential cause. Proven detection methods with high reliability
Very high	2	Very high chance design control will detect potential cause. Proven detection methods available.
High	3	High chance design control will detect potential cause. Detection tools have high chance of detecting methods.
Moderately High	4	Moderately high chance design control will detect potential cause. Almost certain not to detect failure.
Moderate	5	Moderate chance design control will detect potential cause. Detection tools have moderate chance of detecting methods.
Low	6	Low chance design control will detect potential cause. Detection tools have a low chance of detecting failure.
Very Low	7	Very low chance design control will detect potential cause. Detection tools may not detect failure.
Remote	8	Remote chance design control will detect potential cause. Detection tools will probably not detect failure.
Very remote	9	Very remote chance design control will detect potential cause. Detection tools most likely will not detect failure.
Absolute uncertainty	10	No design control, or design control will not detect potential cause. Failure not detected.

Note: Individual contributory factor for each potential failure mode shall be rated. Other scale parameters may also be selected based on the process.

10.0 Acceptance Criteria for Risk Assessment by FMEA:

Acceptance criteria for FMEA are as follows:

Risk Category	Risk Classification (Quantitative) Risk Index	Action Status
High	≥ 500	CAPA required
Medium	126 – 499	CAPA may be required
Low	≤ 125	CAPA not required

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11.0 Risk Assessment as per FMEA:

Name of facility/ Utility/ Equipment / Process/ Operation: Risk assessment study for Replacement of IPC with spare IPC in compression Machine

S.No.	Potential failure mode	Potential failure effects	SEV (S)	Potential causes	OCC (O)	Current Process controls	DET (D)	RPN (SxOxD)	Risk Classification	Actions recommended	Responsibility (target date)	Action Results					
												Action taken	Severity	Occurrence	Detection	New RPN	Risk Classification
1	Improper Installation of New PLC	1. Impact on equipment performance 2.Operation failure 3. PLC may be crashed /hang during operation.	7	1. Ethernet and serial communication with new PLC may not compatible with existing system. 2.Installation of new PLC may not do properly.	2	1.SOP (Computerized system validation) is in place for qualification/ validation of equipment/ instrument. 2. Installation of PLC will be performed by trained Person.	4	56	Low	Addendum Installation and addendum Operation qualification of new PLC shall be carried out as per SOP.	IT/ENGG/ Production/QA						

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												Action taken	Severity	Occurrence	Detection	New RPN	Risk Classification
2.	Documentation	Failure of GMP requirement	6	SOP / Manual/ test /certificate is not available	3	This is GMP and GDP requirement & procedure is available for verification of documents as per SOP.	3	54	Low	Verification of documents shall be carried out during qualification as per SOP	IT/ENGG./ Production/QA						
3.	Communication failure verification of IPC	Operation & product failure	7	Communication failure study not verified	3	Communication failure study procedure is in place to verify any abnormal changes in recipe during communication failure.	4	84	Low	Communication failure study shall be performed during CSV As per SOP.	IT/ENGG./ Production/QA						
4.	Safety interlock	Alarm may not generated	8	New PLC may not compatible to generate Alarm.	3	Operational SOP is available and Critical/Non critical alarm defined in existing operational SOP.	2	48	Low	Alarm shall be verified during addendum operational qualification as per SOP	IT/ENGG.						

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12.0 Risk Control Measures:

Investigation / Findings:

Risk assessment study for replacement of PLC in Autocoater machine is reviewed with current process control and recommended actions.

Corrective Action:

PR initiated for replacement of PLC of same specification.

13.0 Summary & Conclusion Report for Risk Assessment:

Summary:

During risk assessment study various potential failure mode derived and evaluated followed by potential failure effects and potential causes

S.No.	Proposed Action	Responsible Department	TCD
1.	Addendum Installation and addendum Operation qualification of new PLC shall be carried out as per SOP.	Prd/Engg/IT/QA	
2.	Verification of documents shall be carried out during qualification as per SOP.	Prd/Engg/IT/QA	
3.	Communication failure study shall be performed during CSV as per SOP.	Prd/Engg/IT/QA	
4	Alarm shall be verified during addendum operational qualification as per SOP.	Prd/Engg/IT/QA	

Conclusion:

Based on above risk assessment study it is concluded that risk associated is low as per existing current process control and recommended action to be completed for better control and compliance.

14.0 Risk Categorization:

(Product, Process, Equipment, System, Cross Contamination, Data integrity, Quality System module (Change Control, CAPA, Event, OOS, Market Complaint, Batch Release Procedure etc.)) Risk is low and detailed risk assessment has been carried out and shall be attached during risk summarization.

14.1 Risk related to: Equipment

14.2 Risk categorization comments:

Risk is considered low for replacement of PLC in Autocoater machine.

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15.0 Final Report Approval (Pre-Assessment):

The final report shall be signed after identifying all the risks and critical control parameters. All the reports or documents have been attached to the respective report (if applicable).

Signature in the block below indicates that all the control measures are in place/identified, documented and have been reviewed and found to be acceptable.

Responsibility		Name	Signature	Date
Prepared By	**Engineering**			
	Engineering			
	Production			
	Information Technology			
	Quality Assurance			
Approved By	**Head Operations**			
	Head QA			

16.0 Final Report Approval (Post Assessment):

The final report shall be signed after implementing all the recommended actions and based on the implementation of actions, reclassification of risk was completed. All the reports or documents have been attached to the respective report (if applicable).

Signature in the block below indicates. All the control measures taken are documented and have been reviewed and found to be acceptable.

Responsibility		Name	Signature	Date
Prepared By	**Engineering**			
Reviewed By	**Engineering**			
	Production			
	Information Technology			
	Quality Assurance			
Approved By	**Head Operations**			
	Head QA			

17.0 Risk Communication:

The above quality risk assessment is shared with the following process owner and management.

1. Quality Assurance.
2. Information Technology
3. Production
4. Engineering

18.0 Abbreviation:

SOP	:	Standard Operating Procedure
FMEA	:	Failure Mode Effect Analysis
CFR	:	Code of Federal Regulation
QRM	:	Quality Risk Management
QMS	:	Quality Management System
RPN	:	Risk Priority Number
RAS	:	Risk Assessment
SME	:	Subject Matter Expert