RISK ASSESSMENT FOR REPLACEMENT OF EXISTING HMI IN LIQUID FILLING & SEALING MACHINE

RISK ASSESSMENT STUDY

(FMEA ANALYSIS)

FOR

REPLACEMENT OF EXISTING HMI IN LIQUID FILLING & SEALING MACHINE WITH NEW HMI

Document No.:…….

Effective From/Approval Date: ……

Risk Review Due on: …….

Remarks: Risk assessment is prepared based on change control. The activity for replacement of existing HMI of liquid filling & sealing machine having equipment ID ……. through change control procedure and in case in future if again any updation required in filling & sealing machine same shall be done through change control and risk assessment shall be reviewed through that change control.

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1.0 Table of contents:

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2.0 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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3.0 Introduction:

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

4.0 Objective:

The objective of this protocol is to perform the quality risk assessment study in line with the guidance of the risk management manual and ICH Q9 for replacement of HMI of Filling & Sealing machine installed in Liquid area in line with the guidance of the Risk Management of Macleods and ICH Q9.

5.0 Scope:

The purpose 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.

This document provides risk assessment study for replacement of HMI of liquid filling & sealing machine installed in Liquid area to evaluate the mitigation & acceptance risk associated with it.

6.0 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 protection of the patient.
- Various risks associated/anticipated shall be Q9 for replacement of HMI of filling & sealing machine installed in Liquid area.
- The impact of the risks shall be evaluated for the potential risks associated with the existing location. Various methodology/tools of risk analysis shall be used as required.
- The risk & impact shall be assessed for the mitigation measures in place and / or the measures proposed.
- 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 study carried out.
- The control mechanism and the risk communication shall be enforced / verified in the operating documentation.
- The quality risk assessment has been planned for evaluation on the basis of failure mode effect analysis (FMEA) tool.

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☞ The following process /steps have been/ will be followed for risk assessment:

7.0 Responsibilities:

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.

Quality Assurance Department is responsible for review of quality risk assessment and coordinate the QRM team members and they shall be take the decisions about quality risk control & action plan.

Head Operations is responsible for review adequacy of quality risk assessment and approve the final decision taken after recommended action plan.

Quality Assurance Head is responsible for review adequacy of quality risk assessment and approve the final decision taken after recommended action plan.

8.0 Reference Documents:

The relevant Document for monitoring, control is listed below:

- SOP - Quality Risk management.
- SOP - Procedure for handling Breakdown of equipment's.
- SOP - Calibration Policy
- SOP - Change management system
- SOP - Event management
- SOP - Handling of corrective and preventive actions
- SOP - Qualification of Equipment, Facility, Utilities and System
- SOP - Handling of OOS/OOT/Atypical investigations
- SOP - Preventive maintenance of liquid filling & sealing machine anchor mark
- SOP - Cleaning and operation of filling and sealing machine

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9.0 Background:

The facility is producing various ranges of tablets, capsules and oral liquid with the help of required utilities & machineries. On ……. breakdown initiated for HMI not working properly of liquid filling & sealing machine and after engineering person evaluation it is concluded that it cannot be repaired so need to replace with new HMI. Based on the current available process controls, risk severity and probability of occurrence; RPN shall be calculated and risk shall be prioritized. Based on prioritize risk, actions shall be proposed (if any) in order to mitigate the risk.

10.0 Risk Ranking Parameters:

10.1 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.

10.2 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 15,00,000).
Remote	2	Remote, rare number of historical failure(1 in 1,50,000).
Very slight	3	Very few failure likely (1 in 15,000)
Slight	4	Few failure 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)

10.3 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.

11.0 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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12.0 Risk Assessment as per FMEA: Replacement of existing HMI of Liquid Filling & Sealing machine with New HMI

RISK ASSESSMENT BEFORE CONTROL												Action Results						
S. No.	Potential failure mode	Potential failure effects	SEV (S)/ REMARKS	Potential causes	OCC (O) REMARKS	Current process controls	DET (D) REMARKS	RPN (SxOxD)	Risk Classification	Actions recommended	Responsibility (target date)	Actions taken	SEV (S)/ REMARKS	OCC (O) / REMARKS	DET (D) / REMARKS	New RPN	Risk Classification	
1.	Compatibility of PLC with new HMI of equipment.	Equipment performance	5/ Customer experiences some dissatisfaction.	1. HMI may not compatible with PLC system. 2. Ethernet and serial communication with current system may not done. Installation of new HMI may not done properly.	4/ Few failure likely	Procedure for verification of equipment component as well as communication detail during qualification of equipment is available as per SOP which mitigates potential cause of indicated risk.	4/ Almost certain not to detect failure.	**80**	Low	PLC validation of new HMI shall be carried out including the test as interlocking, boundary range, access right etc.	Prd./Engg./QA							
2.	Parameter Visibility	Failure in equipment performance or efficiency.	5/ Customer experiences some dissatisfaction.	1. Operating sequence verification of equipment during qualification may not accomplished. 2. Communication error from field instrument.	4/ Few failure likely	Procedure for components verification and operating sequence is in place as per respective SOP which mitigates the potential cause of identified risk.	3/ Detection tools have high chance of detecting methods.	**60**	Low	Operating sequence, boundary range and access level shall be verified during equipment qualification and PLC validation.	Prd./Engg./QA							

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RISK ASSESSMENT BEFORE CONTROL												Action Results					
Sr. No.	**Potential failure mode**	**Potential failure effects**	**SEV (S)/ REMARKS**	**Potential causes**	**OCC (O) REMARKS**	**Current process controls**	**DET (D) REMARKS**	**RPN (SxOxD)**	**Risk Classification**	**Actions recommended**	**Responsibility (target date)**	**Actions taken**	**Severity**	**Occurrence**	**Detection**	**New RPN**	**Risk Classification**
3.	Controlling by PLC	Equipment failure	5/ Customer experience some dissatisfaction.	1. HMI malfunctioning. 2. Communication Failure	5/ Occasional number of failures likely	1. Verification procedure for key functionality for HMI is available as per SOP 2. Controlling parameter verification procedure available.	3/ Detection tools have high chance of detecting methods.	**75**	Low	Key functionality of HMI shall be verified during OQ activity and controlled parameter operation shall be verified during qualification.	Prd./Engg./QA						
4.	Power failure verification of HMI	Operation & product failure	5/ Customer experiences some dissatisfaction.	Power failure study not verified	4/ Few failure likely	Power failure study procedure is in place to verify any abnormal changes in recipe during power cut off.	4/ Almost certain not to detect failure.	**80**	Low	Power failure study shall be performed during qualification of equipment	Prd./Engg./QA						

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RISK ASSESSMENT BEFORE CONTROL												Action Results					
Sr. No.	**Potential failure mode**	**Potential failure effects**	**SEV (S)/ REMARKS**	**Potential causes**	**OCC (O) REMARKS**	**Current process controls**	**DET (D) REMARKS**	**RPN (SxOxD)**	**Risk Classification**	**Actions recommended**	**Responsibility (target date)**	**Actions taken**	**Severity**	**Occurrence**	**Detection**	**New RPN**	**Risk Classification**
5.	Communication failure verification of HMI	Operation & product failure	5/ Customer experiences some dissatisfaction.	Communication failure study not considered in qualification.	4/ Few failure likely	1. Communication failure study procedure is in place to verify any abnormal changes in parameters during communication lost. 2. Control loop test or parameters verification is a part of qualification procedure.	4/ Almost certain not to detect failure.	**80**	Low	Communication failure study shall be performed during qualification and PLC validation activity.	Prd./Engg./QA						
6.	Failure in Function of HMI	Operation failure	5/ Customer experiences some dissatisfaction.	Malfunctioning of PLC with respect to HMI	4/ Few failure likely	1. SOP is in place for equipment qualification. 2. Operational sequence verification procedure available during qualification of equipment.	4/ Almost certain not to detect failure.	**80**	Low	Qualification of new HMI shall be carried out as per SOP.	Prd./Engg./QA						

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RISK ASSESSMENT BEFORE CONTROL											Action Results					
S. No.	Potential failure mode	Potential failure effects	SEV (S)/ REMARKS	Potential causes	OCC (O) REMARKS	Current process controls	DET (D) REMARKS	RPN (SxOxD)	Risk Classification	Actions recommended	Responsibility (target date)	Actions taken	Severity	Occurrence	Detection	New RPN	Risk Classification
7.	Installation of new HMI	Operation failure	4/Customer experiences minor nuisance.	Installation not done properly	4/ Few failure likely	Procedure for installation qualification is in place to verify the installed components.	4/ Almost certain not to detect failure.	64	Low	Qualification of new HMI shall be carried out.	Prd./Engg./QA						
8.	Impact on operation procedure due to change of Existing HMI with new HMI	Operation Failure	4/Customer experiences minor nuisance.	Operation procedure not available or change in HMI may leads to operation failure	5/ Occasional number of failures likely	1.Procedure for operation of liquid filling & sealing machine is available as per SOP. 2.There is no change in program and same shall be verified during qualification as per SOP.	4/ Almost certain not to detect failure.	80	Low	Operation Procedure shall be verified during qualification activity as per SOP.	Prd./Engg./QA						
9.	Qualification	Failure of GMP requirement	3 Slight effect on performance	Unqualified HMI may be used	4/ Few failure likely	Procedure for qualification of equipment is available as per SOP	4/ Almost certain not to detect failure.	48	Low	Qualification of HMI of liquid filling & sealing machine shall be carried out as per SOP	Prd./Engg./QA						

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13.0 Risk Control Measures:

Investigation / Findings:

- HMI of liquid filling & sealing machine shall be replaced with new HMI.

Corrective Action:

- Change control PR initiated for the replacement of HMI of liquid filling & sealing machine.

14.0 Summary & Conclusion Report for Risk Assessment:

Summary:

Available control measures are sufficient to mitigate the risk of contamination and cross contamination. However, for further mitigation of risk below are the recommended actions.

S.No.	Proposed Action	Responsible Department	TCD
1.	PLC validation of new HMI shall be carried out including the test as interlocking, boundary range, access right etc.	Engineering / Production / Quality Assurance	
2.	Operating sequence, boundary range and access level shall be verified during equipment qualification and PLC validation.		
3.	Key functionality of HMI shall be verified during OQ activity and controlled parameter operation shall be verified during qualification		
4.	Power failure study shall be performed during qualification of equipment		
5.	Communication failure study shall be performed during qualification and PLC validation activity.		
6.	Qualification of new HMI shall be carried out as per SOP.		
7.	Qualification of new HMI shall be carried out.		
8.	Operation Procedure shall be verified during qualification activity as per SOP		
9.	Qualification of HMI of liquid filling & sealing machine shall be carried out as per SOP		

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.

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 taken are documented and have been reviewed and found to be acceptable.

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Responsibility		Name	Signature	Date
Prepared by	**Engineering**			
Reviewed by	**Engineering**			
	Production			
	Quality Assurance			
Approved by	**Head - Operation**			
	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			
	Quality Assurance			
Approved by	**Head - Operation**			
	Head - QA			

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17.0 Risk Communication:

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

1. Quality Assurance.
2. Production
3. Engineering

18.0 Abbreviation:

SOP : Standard Operating Procedure

FMEA : Failure Mode Effect Analysis

QRM : Quality Risk Management

QMS : Quality Management System

CAPA : Corrective Action and Preventive Action

RPN : Risk Priority Number

ICH : International Conference on Harmonization

RAS : Risk Assessment

HMI : Human Machine Interface