RISK ASSESSMENT STUDY

(FMEA ANALYSIS)

FOR

REPLACEMENT OF HMI OF RMG

Document No.:

Effective From/Approval Date: ……

RISK ASSESSMENT FOR REPLACEMENT OF HMI OF RMG

1.0 Table of contents:

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2.0 Quality risk assessment team:

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.

On dated ……. breakdown intimation was initiated by production department for data not shown in HMI of RMG. During utility evaluation it was observed that manual power on/off selector switch of HMI may be the probable root cause for data not shown in HMI of RMG, also HMI is of old version and may be not compatible with printer hence need to be replaced with new HMI of same specification.

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 RMG installed in facility.

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 Q9 for replacement of HMI of RMG facility 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 RMG in facility.
- ☞ 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 and coordinate the QRM team members and they shall be take the decisions about quality risk control & action plan.

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

Quality Assurance Department is responsible for review of quality risk assessment procedure and support to its execution.

Head Operation is responsible for review of quality risk assessment procedure.

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- Handling of Corrective Action & Preventive actions.
- SOP- Quality Risk management.
- SOP- Cleaning of production area.
- SOP- Fumigation in Production area.
- SOP- Training of Personnel.
- SOP- Preventive maintenance of RMG.
- SOP- Operation & Cleaning Procedure of RMG.
- SOP- Performing of equipment validation qualification.

9.0 Background:

The facility is producing various ranges of tablets, capsules and oral liquid with the help of required utilities & machineries. On dated ……..breakdown intimation was initiated by production department for data not shown in HMI of RMG. During utility evaluation it was observed that manual power on/off selector switch of HMI may be the probable root cause for data not shown in HMI of RMG, also HMI is of old version and may be not compatible with printer hence need to be replaced with new HMI of same specification. 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.

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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 Post-Risk Assessment as per FMEA:

RISK ASSESSMENT BEFORE CONTROL												Action Results					
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)**	**Actions taken**	**Severity**	**Occurrence**	**Detection**	**New RPN**	**Risk Classification**
1.	Compatibility of HMI with equipment.	Equipment performance	5	1. HMI may not verified during Qualification. 2. Ethernet and serial communication with current system. 3. Power supply compatibility with HMI. 4. Installation of new HMI may not done properly. 5. Required Utility may not provide.	4	Procedure for verification of equipment component during qualification of equipment is available as per SOP.	4	80	Low	Qualification of new HMI shall be carried out as per SOP.	Prd./Engg./ QA						
2.	Parameter Visibility	Equipment performance	5	1. Operating sequence verification of equipment during qualification may not carried out. 2. Software version may not compatible with existing system. 3. Communication error from field instrument.	4	1. Operating sequence verified during equipment qualification as per SOP. 2. Qualification procedure available for PLC & IPC based computerized system as per SOP.	3	60	Low	Operating sequence shall be verified during equipment qualification.	Prd./Engg./ QA						

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Sr. 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)**	**Actions taken**	**Severity**	**Occurrence**	**Detection**	**New RPN**	**Risk Classification**
3.	Operating structure	Operation Failure	5	1. Unavailability of operating manual. 2. Improper program downloading	4	1. Operating manual of equipment is available for smooth operation of equipment. 2. Trained men power for operation on machine is available.	4	**80**	Low	Qualification of new equipment shall be carried out as per SOP.	Prd./Engg./ QA						
4.	Improper handling of HMI.	Equipment performance	5	1. Fitting of HMI not done properly. 2. Periodic verification of equipment not carried out as per schedule	5	1. HMI is provided inside SS enclosure. 2. SOP for operation & Cleaning of RMG is available. 3. SOP For Preventive maintenance is available. 4. SOP for requalification is available.	3	**75**	Low	NA	NA						
5.	Motor controlling by HMI	Equipment failure	5	1. HMI malfunctioning. 2. Communication Failure	5	1. Verification procedure for key functionality of control panel or HMI is available. 2. Controlling parameter verification procedure available.	3	**75**	Low	1. Key Functionality of HMI shall be verified during qualification of equipment. 2. Controlling parameter functioning shall be verified during qualification of equipment.	Prd./Engg./ QA						

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6.	Power failure verification on HMI	Operation Failure	5	Power failure study not verified	4	Power failure study procedure is in place to verify any abnormal changes in recipe during power cut off.	4	**80**	Low	Power failure study shall be performed during qualification	Prd./Engg./ QA						
7.	Communication failure verification on HMI	Product failure	5	Communication failure study not considered in qualification.	4	1. Communication failure study procedure is in place to verify any abnormal changes in recipe during communication lost. 2. Control loop test or recipe verification is a part of qualification procedure.	3	**60**	Low	Communication failure study shall be performed during qualification	Prd./Engg./ QA						
8.	Audit trail	Audit trial of batch record may not generated	5	New HMI may not compatible for taking audit trial	5	1. HMI verified during qualification by generating audit trial. 2. Procedure for audit trial verification is in place during qualification of equipment.	3	**75**	Low	Audit trial shall be verified during qualification.	Prd./Engg./ QA						
9.	Individual login	Product failure	5	1. New HMI may not compatible for individual login compatibility 2. Recipe may be alter by other person	4	1. Individual login are provided for different users. 2. Procedure for individual login is available with HMI.	4	**80**	Low	Compatibility of individual login shall be verified during qualification.	Prd./Engg./ QA						
10.	Failure in Function of HMI touch keys	Operation failure	5	1. Improper verification of HMI keys 2. Malfunctioning of new HMI in term of delay time, RPM of impeller & chopper motor etc. 3. Printout of recipe not matched with commanded input. 4. Improper opening & closing of top lid and discharge lid as per requirement.	4	1. Procedure of verification of HMI touch keys is available during qualification. 2. Boundary test procedure of specific parameter is in place during csv. 3. SOP is in place for equipment qualification. 4. Verification procedure of print out with respect to decided recipe is in place during qualification. 5. Operational sequence verification procedure available during qualification of equipment.	4	**80**	Low	Qualification of new HMI shall be carried out.	Prd./Engg./ QA						

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RISK ASSESSMENT BEFORE CONTROL												Action Results					
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)	Actions taken	Severity	Occurrence	Detection	New RPN	Risk Classification
11.	Unique User ID and Password	Product failure	5	Nonfunctioning of unique user ID feature may result into access of unauthorized user to the system due to common ID and password.	4	1. Procedure in place for verification of unique user ID during GXP system validation. “Computerized System Validation”) however; it was not performed during PLC validation. 2. Documented procedure available “User management and password policy” for ID/Password creation and granting access to the users.	4	80	Low	1. Unique user ID shall be created for all individual users and that shall be used during operation of equipment. 2. Unique user ID verification shall be performed during qualification.	Prd./Engg./ QA						

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RISK ASSESSMENT BEFORE CONTROL											Action Results					
Sr. 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)**	**Actions taken**	**Severity**	**Occurrence**	**Detection**	**New RPN**	**Risk Classification**
12.	Password Complexity	Small password policy may result into easy access of the system by unauthorized users.	5	Lack of procedures	4	Procedure is defined for minimum length of password in SOP “User management and password policy” but didn’t enforce.	4	80	Low	Facility for minimum length of strong password shall be verified during qualification i.e. password length should be 1 to 32 characters and complexity of password with capital letter, small letter, number and special character.	Prd./Engg./ QA						
13.	Password – aging (expiry) facility	Keeping same password for long period of time increases risk of password breach by unauthorized user.	5	Due to lack of procedures.	4	Procedure is available for user management and password policy “User management and password policy”.	4	80	Low	For Equipment, password – aging (expiry) feature and CSV for this feature shall be performed as per SOP “Computerized System Validation”.	Prd./Engg./ QA						

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13.0 Risk Control Measures:

Investigation / Findings:

- HMI of RMG shall be replaced with new HMI of same specification.
- On/Off Selector switch of HMI of RMG shall be removed.

Corrective Action:

- Change control PR#99410 initiated for the replacement of HMI of RMG. On/Off Selector switch of HMI of RMG shall be removed.
- SOP for Cleaning and operation of rapid mixer granulator with co-mill and peristaltic pump (capacity 100 liters) Make Gansons shall be revised.

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.	Qualification of new HMI shall be carried out as per SOP.	Engineering / Production / Quality Assurance	
2.	Operating sequence shall be verified during equipment qualification.		
3.	1. Key Functionality of HMI shall be verified during qualification of equipment. 2. Controlling parameter functioning shall be verified during qualification of equipment.		
4.	Power failure study shall be performed during qualification		
5.	Communication failure study shall be performed during qualification		
6.	Audit trial shall be verified during qualification.		
7.	Compatibility of individual login shall be verified during qualification.		
8.	1. Unique user ID shall be created for all individual users and that shall be used during operation of equipment. 2. Unique user id verification shall be performed during qualification.		
9.	Facility for minimum length of strong password shall be verified during qualification i.e. password length should be 1 to 32 characters and complexity of password with capital letter, small letter, number and special character.		
10.	For Equipment, password – aging (expiry) feature and CSV for this feature shall be performed as per SOP “Computerized System Validation”.		

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.

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