R I S K A S S E S S M E N T S T U D Y

(F M E A A N A L Y S I S)

F O R

DOOR REPLACEMENT AND REPOSITIONING IN MANUFACTURING AREA

Document No.: ……

Effective From / Approval Date: ……

Risk Review due on: NA

Remarks: Risk assessment is prepared based on change control. The activity for door replacement and repositioning of manufacturing area handled through change control procedure and in case in future if any modification of door required same shall be done through change control and risk assessment shall be reviewed through that change control

RISK ASSESSMENT FOR DOOR REPLACEMENT AND REPOSITIONING OF MANUFACTURING AREA

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.

Sr. No.	Team Member	Department	Designation	Sign/Date

HOD Approval

Name	Department	Designation	Sign & Date

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3.0 Introduction:

The General block (GB) manufacturing facility is a tablet, capsule and oral liquid producing facility. 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 door replacement and repositioning in manufacturing area.

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 ICH for door replacement and repositioning in manufacturing area.

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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 ICH Q9 for door replacement and repositioning in manufacturing 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.
- 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 review of quality risk assessment procedure and support to its execution.

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

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

Head Operation is responsible to check the adequacy of quality risk assessment and approve the final decision taken after recommended action plan.

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

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8.0 Reference Documents:

The relevant Document for monitoring, control is listed below:

- SOP- Handling of Corrective Action & Preventive actions.
- SOP- Change management system
- SOP- Event management
- SOP- Quality Risk management.
- SOP- Procedure for general maintenance work.
- SOP- Qualification of Equipment, Facility, Utilities and System
- SOP- Procedure for work permit
- SOP- Procedure for Preventive Maintenance of Building Facility.
- SOP- Procedure for Microbial air monitoring.
- SOP- Fumigation in Production Area.
- SOP- Cleaning of production area

9.0 Background:

The facility is producing various ranges of tablets, capsules and oral liquid with the help of required utilities & machineries. Risk assessment study shall be performed to find out potential failure causes during door replacement and repositioning in manufacturing area. List of impacted Door & repositioning is attached as Attachment-I & Work flow for performing activity is attached as Attachment-II.

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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	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	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:-

Name of facility/Utility/Equipment/Process/Operation: Door replacement and repositioning in manufacturing area

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)	Action Results					
												Actions taken	SEV (S)/ REMARKS	OCC (O) / REMARKS	DET (D) / REMARKS	New RPN	Risk Classification
1.	- Injury to man during shifting of new doors and removal of existing doors.	- Accident may occur which lead to harm to persons involve in activity.	6 (Significant severity)	-Unavailability of EHS policy and procedure may cause lack of trained manpower which may leads to the accident. -Insufficient manpower may cause the accident. -Improper handling may cause the accident.	4 (Slight probability of occurrence).	-EHS policy is in place as per SOP having tittle “Procedure for work permit”. - Procedure for handling of accident and incident is in place as per SOP having tittle “Procedure for accident & incident handling”. -Personnel protective equipment’s are available which alleviates the risk of health hazard during accident. -Sufficient and trained manpower is available for handling of equipment which alleviates the probable risk of accident.	4 (Moderately high detection).	96	Low	-It is recommended to initiate the Work permit for safety precautions before execution of activity as per SOP.	Prod /ENG.						

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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)	Action Results					
												Actions taken	SEV (S)/ REMARKS	OCC (O) / REMARKS	DET (D) / REMARKS	New RPN	Risk Classification
2.	Consequences of Civil activity performed during replacement of door	Area Contamination Environmental condition may disturb Product failure	5/ Customer experience some dissatisfaction.	**1**. During installation minor civil activity shall be performed. This causes area contamination. **2**. Material kept in blend quarantine may contaminate and presence of unauthorized personnel may leads to product mix-ups. **3.** Absence of door may leads to disturbing of environmental condition	4/ Few failure likely	**1**. Area shall be shut down before door installation Activity. **2.**Cleaning procedure is in place as per SOP "Cleaning of production area") **3**. Procedure is in place to perform the activity as per SOP. **4**. AHU requalification procedure is in place as per approve Protocol No.	3/ Detection tools have high chance of detecting methods.	**60**	low	After completion of activity cleaning shall be performed. During execution of proposed activity i.e. Door replacement and door repositioning in Quarantine areas, the material movement shall be done to Another Quarantine areas with inward outward and after completion of proposed activity same shall be shifted to existing location with inward outward respectively. AHU requalification of respective area shall be performed after completion of activity.	Prod /ENG.						

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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)	Action Results					
												Actions taken	SEV (S)/ REMARKS	OCC (O) / REMARKS	DET (D) / REMARKS	New RPN	Risk Classification
3.	Entry and exit of personnel in Quarantine areas, and other impacted manufacturing areas during installation of New door & repositioning of door.	Cross contamination Uncontrolled movement	5/ Customer experience some dissatisfaction.	1.Unavailability of biometric finger Access controller may leads to entry of Unauthorized person in l quarantine & impacted manufacturing areas **2**.Authorized person not able to enter in the area to perform the routine activity as biometric finger access controller not installed after door replacement **3**. Procedure not available for entry and exit in absence of biometric finger access controller	4/ Few failure likely	1. Procedure is in place to close the Work order and completion of all activity as per SOP. 2. Area shall be shut down before door installation and door removal Activity. 3. Challenge test for biometric access is in place. 4. Procedure for Biometric finger access is in place as per SOP 'Entry and Exit of Personnel in core area through access control system' as per SOP point 5.1.9 in case of breakdown in access controller manual entry shall be done with authorized person.	3/ Detection tools have high chance of detecting methods.	**60**	LOW	Biometric Access controller wiring/fitting shall be reinstall after replacement & repositioning of door and challenge shall be performed accordingly	Prod /ENG.						

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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)	Action Results					
												Actions taken	SEV (S)/ REMARKS	OCC (O) / REMARKS	DET (D) / REMARKS	New RPN	Risk Classification
4.	Disturbance of environmental condition of adjacent area due to civil activity.	Microbial contamination Failure of environmental condition of specific area	4/Customer experiences minor nuisance.	**1.** Due to ongoing civil activity adjacent area is in working condition which cause cross contamination and failure of environmental condition.	5/ Occasional number of 4/ Few failure likely	1. Procedure is in place for monitoring of environmental condition of area at regular intervals as per SOP. 2. Procedure is in place for Work order and completion of all activity as per SOP Area shall be shut down before door installation and door removal Activity. 3. Microbiological monitoring of manufacturing area is in place SOP "Procedure for microbial air monitoring'). 4. Work flow for each activity is available and attached with PR. 5. AHU Requalification procedure is in place as per approved protocol.	4/ Almost certain not to detect failure	**64**	LOW	During civil activity adjacent corridors shall be shut down and properly sealed with running ahu. After completion of activity, fumigation, cleaning, Non-viable particle count, microbial plate's exposure shall be done in impacted areas and adjacent areas with respect to area where door replacement activities shall be performed. Area shall be released based on non-viable particle count reports for manufacturing activities and viable monitoring shall be performed in dynamic conditions and product manufactured in impacted areas shall be release after satisfactory results of viable monitoring	Prod /ENG.						

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13.0 Risk Control Measures:

Investigation / Findings:

Proposal for door replacement and repositioning in manufacturing area reviewed with current process control.

Corrective Action:

NA

14.0 Summary & Conclusion Report for Risk Assessment:

Summary:

Available control measures are sufficient to mitigate the risk of contamination and cross contamination against proposal.

S.No.	Proposed Action	Responsible Department	TCD
1.	Work order required for required utility	Engineering	
2.	During execution of proposed activity i.e. Door replacement and door repositioning in Quarantine areas, the material movement shall be done to Another Quarantine areas with inward outward and after completion of proposed activity same shall be shifted to existing location with inward outward respectively.	Engineering	
3.	Biometric Access controller wiring/fitting shall be reinstall after replacement & repositioning of door and challenge shall be performed accordingly	Engineering	
4.	After completion of activity, fumigation, cleaning, Non-viable particle count, microbial plate's exposure shall be done in impacted areas and adjacent areas with respect to area where door replacement activities shall be performed. Area shall be released based on non-viable particle count reports for manufacturing activities and viable monitoring shall be performed in dynamic conditions and product manufactured in impacted areas shall be release after satisfactory results of viable monitoring	Engineering	

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.

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15.0 Risk categorization:

(Product**,** Process, Equipment, System, cross contamination, data integrity, Quality system modules (Change control, CAPA, Event, OOS, Market complaint, Batch release procedure etc.)

Risk is major and detailed risk assessment shall be carried out and attached during risk summarization.

15.1 Risk related to: Change control

15.2 Risk categorization comments:

Change is related to door replacement and repositioning of manufacturing area

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16.0 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			
	QC			
	Quality Assurance			
Approved by	**Head - Operation**			
	Head - QA			

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17.0 Final Report Approval (Post 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			
	QC			
	Quality Assurance			
Approved by	**Head - Operation**			
	Head - QA			

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18.0 Risk Communication:

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

1. Quality Assurance.
2. Production
3. Engineering
4. QC

19.0 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