RISK ASSESSMENT STUDY

(FMEA ANALYSIS)

FOR

PROVISION OF DIRTY FILTER ROOM IN HVAC AREA

Document No.: …….

Effective From / Approval Date: ……

Risk Review due on: NA

Remarks: Risk assessment is prepared based on change control. The activity for provision of dirty filter room in HVAC area through change control procedure and in case in future if again any provision in any other area required same shall be done through different change control and risk assessment shall be reviewed through that change control

RISK ASSESSMENT FOR PROVISION OF DIRTY FILTER ROOM IN HVAC AREA

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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 required utility & equipment's.

3.0 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 Risk Assessment study for provision of Dirty filter room in HVAC due to collaboration with automated duct cleaning system.

4.0 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 provision of Dirty filter room in HVAC and evaluate the risk related impact on operation and related documents.

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 protection of the patient.
- Various risks associated / anticipated shall be ICH Q9 for Risk Assessment study for provision of Dirty filter room in HVAC.
- 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:

6.0 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.

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

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

Head Operations 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.

7.0 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- Procedure for Equipment validation (Equipment qualification)
- SOP- Preventive maintenance of HVAC system
- SOP- Operation of Air handling unit.
- SOP- Handling of layout

8.0 Background:

The facility is producing various ranges of tablets, capsules and oral liquid with the help of required utilities & machineries. CAPA approved against observation In Warehouse, There was no separate dirty filter room available at HVAC area. As per proposal provision of Dirty filter room in HVAC shall be done.

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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 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)

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: Provision of New dirty filter room in HVAC 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 Civil activity performed for provision of dirt filter room at HVAC area	- Accident may occur which lead to harm to persons involve in activity.	5/ Customer experiences some dissatisfaction.	-Unavailability of EHS policy and procedure may cause lack of trained manpower which may leads to the accident. -Insufficient manpower may cause the accident.	4/ Few failure likely	-EHS policy is in place as per SOP having title "Procedure for work permit". - Procedure for handling of accident and incident is in place as per SOP having title "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 civil activity which alleviates the probable risk of accident.	4 (Moderately high detection).	**80**	**Low**	-It is recommended to initiate the general maintenance Work permit and safety work permit to perform the activity.	ENG./QA						

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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.	Impact on Filter cleaning during civil activity	Cross contamination. Product failure	5/ Customer experience some dissatisfaction.	1) Due to civil activity in HVAC area filter cleaning activity may halted or impacted which leads to mix-up of clean or unclean filters. 2) Activity performed in running condition which causes the contamination 3)Provision not available to store the clean filter	4/ Few failure likely	1) The activity for creation of Dirty filter room area in shutdown condition Additionally procedure is available to keep unclean filter in double poly bag or shrink-wrap. Procedure for cleaning of unclean filter is available as per SOP/BA/ENG/178'Filter cleaning procedure. Person carrying out the activity are trained. 2) Procedure is available for segregation of clean and unclean filter and separate area is available for storage of clean filter	3/ Detection tools have high chance of detecting methods.	**60**	Low	1) It is recommended Work order shall be initiated to carry out activity.	30/07/23 ENG./QA						

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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.	Documentation	Operation failure Impact on Good document practice	4/Customer experiences minor nuisance.	Person not aware about the activity. Filter cleaning Procedure not modified as per proposal for new dirty filter room Procedure not available to revision of layout after modification.	5/ Occasional number of failures likely	Procedure is available for filter cleaning as per SOP 'Filter cleaning procedure. Procedure is available to track the training of concerned person as per PLMS System as per SOP. Procedure to revised the layout is available after completion of activity as per SOP' Handling of Layout'. .	4/ Almost certain not to detect failure	80	Low	Layout shall be Revised. Training shall be imparted to concerned persons for SOP.	Prod /ENG./Warehouse/QA						

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12.0 Risk Control Measures:

Investigation / Findings:

Proposal for review for provision of new dirty filter room is reviewed with current process control.

Corrective Action:

NA

13.0 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 shall be initiated to carry out activity. Shut down area shall be required as per Tentative Date Provided In Work order.	Engineering	
4.	Layout shall be revised. Training shall be provided.	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.

14.0 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.

14.1 Risk related to: Facility

14.2 Risk categorization comments:

Change is related to facility to perform civil activity

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

Responsibility		Name	Signature	Date
Prepared by	**Engineering**			
Reviewed by	**Engineering**			
	EHS			
	Quality Assurance			
Approved by	**Head - Operations**			
	Head - QA			

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16.0 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**			
	EHS			
	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. Engineering
3. EHS

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
AZDV : Actuated Zero dead leg valve