RISK ASSESSMENT STUDY

(FMEA ANALYSIS)

FOR

PROVISION OF INLET TEMPERATURE HIGH ALARM IN FBD

Document No.:

Effective From / Approval Date: ……

Risk Review due on:

Remarks:

RISK ASSESSMENT FOR PROVISION OF INLET TEMPERATURE HIGH ALARM IN FBD

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 provision of Inlet temperature high alarm in FBD 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 ICH Q9 for provision of Inlet temperature high alarm in FBD in facility.

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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 provision of Inlet temperature high alarm in FBD.
- 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.

IT 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- Quality Risk management.
- SOP- Procedure for general maintenance work.
- SOP- Procedure for microbial air monitoring.
- SOP- Cleaning of production area.
- SOP- Procedure for Equipment validation (Equipment qualification)
- SOP- Preventive maintenance of FBD
- SOP- Computer System Validation
- SOP- Cleaning and Operation of Fluidized Bed Dryer (FLUIDAIRE-250)

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 for provision of Inlet temperature high alarm in FBD in facility, for improvement in existing system and to reduce the breakdown time during the batch processing.

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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: Provision of Inlet temperature high alarm in FBD.

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.	Software updation for inlet temperature high alarm	Operation failure Product failure	5/ Customer experiences some dissatisfaction.	1. Updation of software may get impact on other parameters. Besides this lack of CSV may leads to malfunctioning of equipment. 2. During updation software may malfunctioning. .	4/ Few failure likely	1. Procedure for equipment qualification is in place as per SOP having title,' Procedure for Equipment validation (Equipment qualification)' is in place, which mitigates the potential cause of identified risk. 2. Procedure for computerized system verification is in place as per SOP having title, 'computerized system validation'.	3/ Detection tools have high chance of detecting methods.	**60**	Low	It is recommended to perform addendum qualification & addendum CSV after updation of software.	Prd./Engg.						

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												Actions taken	SEV (S)/ REMARKS	OCC (O) / REMARKS	DET (D) / REMARKS	New RPN	Risk Classification
2.	Inadequate performance of equipment and its instruments	Product failure	5/ Customer experiences some dissatisfaction.	M/c may malfunction due to incompatible software programme.	4/ Few failure likely	1. Previous PLC validation is available. 2. Machine functioning is verified during the qualification activity as per SOP having title,' Procedure for Equipment validation(Equipment qualification)'	3/ Detection tools have high chance of detecting methods.	**60**	Low	It is recommended to verify all the performance & machine functioning during qualification as per SOP after updating software program.	Prd./Engg./QA/IT						
3.	Parameter Visibility may impact due to addition of inlet high alarm	Failure in equipment performance or efficiency.	5/ Customer experiences some dissatisfaction.	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/ Few failure likely	1. Procedure for components verification and operating sequence is in place as per respective SOP having title,' Procedure for Equipment validation (Equipment qualification)' Which mitigate the potential cause of identified risk. 2. Procedure for CSV validation is in place as per SOP, having title, 'computerized system validation.	3/ Detection tools have high chance of detecting methods.	**60**	Low	Component verification & operating sequence shall be verified during qualification as per SOP.	Prd./Engg./QA/IT						

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												Actions taken	SEV (S)/ REMARKS	OCC (O) / REMARKS	DET (D) / REMARKS	New RPN	Risk Classification
4.	Controlling by PLC may impact due to addition of inlet high alarm	Equipment failure	5/ Customer experiences some dissatisfaction.	1. HMI software malfunctioning. 2. Communication Failure	5/ Occasional number of failures likely	1. Verification procedure for key functionality of control panel or HMI software is available as per SOP having title,' Procedure for Equipment validation (Equipment qualification)' 2. Controlling parameter verification procedure available.	3/ Detection tools have high chance of detecting methods.	**75**	Low	Key functionality of control panel shall be verified during OQ activity and controlled parameter operation shall be verified during qualification as per SOP.	Prd./Engg./QA/IT						
5.	Failure in Functioning of machine	Operation failure	5/ Customer experiences some dissatisfaction.	M/c may malfunction due to incompatible software programme. Printout of recipe not matched with commanded input.	4/ Few failure likely	1. SOP having title,' Procedure for Equipment validation (Equipment qualification)' is in place for equipment qualification. 2. Verification procedure of print out with respect to decided recipe is in place during qualification. 3. Operational sequence verification procedure available during qualification of equipment.	4/ Almost certain not to detect failure.	**80**	Low	Addendum qualification shall be carried out as per SOP	Prd./Engg./QA/IT						

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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
6.	Alarm verification	Operation failure Product failure	5/ Customer experiences some dissatisfaction.	1. Inlet temperature high alarm not comes and product may be impacted due to this. 2. Operator not aware about the changes in software.	4/ Few failure likely	1. Procedure for verification of alarm during qualification is in place as per SOP having title,' Procedure for Equipment validation (Equipment qualification)' 2. SOP with title Cleaning and Operation of Fluidized Bed Dryer (FLUIDAIRE-250) for operation of fluid bed dryer is available. Training Mechanism is available for any changes in SOP.	4/ Almost certain not to detect failure	**80**	Low	Verification of alarm during qualification shall be carried out as per SOP. SOP Shall be revised for changes made for inlet temperature high alarm.	Prd./Engg./QA/IT						
7.	Documentation	1.Lack of supporting documents 2.Product failure 3.Inadequate performance of equipment	4/Customer experiences minor nuisance.	1. Failure of GMP Requirement. 2. Test certificate may not available or verified.	5/ Occasional number of failures likely	1. Procedure for verification of documents is available as per respective SOP 2. All supportive documents attached with respective qualification documents after verification or reviewed by concern personnel.	4/ Almost certain not to detect failure	**80**	Low	Documents along with test certificate or supportive documents shall be verified during qualification activity as per SOP	Prd./Engg./QA/IT						

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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
8.	1.Impact on updation of History card against equipment HMI updation 2. Impact on Calibration of inlet temperature sensor.	Failure in GDP requirement.	4/Customer experiences minor nuisance.	History card may not be updated after activity. - Calibration planner not updated after provision of inlet temperature high alarm.	3 / Very few failure likely	1. Procedure for updation of History card of equipment is in place as per SOP having tittle “Procedure for breakdown maintenance”. 2. Inlet temperature sensor is already calibrated. Hence no impact on calibration of sensor.	**3** /Very slight occurrence	**36**	Low	History card shall be updated,	Prd./Engg./QA/IT						

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13.0 Risk Control Measures:

Investigation / Findings:

Proposal for provision of Inlet temperature high alarm in FBD in 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.	Addendum CSV shall be carried out as per SOP	IT	
2.	Key functionality of control panel shall be verified during OQ activity and controlled parameter operation shall be verified during qualification.	Engineering	
3.	SOP Shall be revised for changes made for inlet temperature high alarm	Production	
4.	History card shall be updated,	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.

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: Equipment

15.2 Risk categorization comments:

Change is related to updation of HMI program in FBD.

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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			
	IT			
	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			
	IT			
	Quality Assurance			
Approved by	**Head - Operation**			
	Head - QA			

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. IT

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