RISK ASSESSMENT FOR IMPELLER END POINT CURRENT MINIMUM & MAXIMUM PARAMETER SHIFT FROM RECIPE PARAMETER TO MACHINE PARAMETER IN EQUIPMENT

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

IMPELLER END POINT CURRENT MIN.& MAX. PARAMETER SHIFT FROM RECIPE PARAMETER TO MACHINE PARAMETER IN EQUIPMENT

Document No.: ……

Effective From/Approval Date: ……

Risk Review Due on: …….

Remarks:

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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 require utility & equipment's.

4.0 Objective:

The objective of this protocol is to perform the Quality Risk assessment study for impeller end point current min.& max. parameter shift from recipe parameter to machine parameter in equipment, in line with the guidance of the Risk Management and ICH Q9.

5.0 Scope:

The scope 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.

The scope of this assessment is limited to identify evaluate & provide controlling measure (if required) against the risk associated for impeller end point current min.& max. parameter shift from recipe parameter to machine parameter in equipment as well as evaluates the mitigation & acceptance the risk associated with it.

6.0 Risk assessment approach:

- 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 for shifting of parameter for impeller end point current min.& max. parameter shift from recipe parameter to machine parameter in equipment.
- The impact of the risks shall be evaluated for the potential risks associated with the existing location. As required various methodology / tools of risk analysis shall be used.
- The risk & impact shall be assessed for the mitigation measures in place and / or the measures proposed.
- 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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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.

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

Head Engineering / Designee 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

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

Quality Assurance Head / **Designee** 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 SOP's & Document for monitoring, control are listed below: SOP's,

- SOP - Quality Risk management.
- SOP - Procedure for handling Breakdown of equipment's.
- SOP - User Management and Password Policy
- SOP - Change management system
- SOP - Event management
- SOP - Handling of corrective and preventive actions
- SOP - Qualification of Equipment, Facility, Utilities and System
- SOP - Preventive maintenance of Rapid mixer granulator
- SOP - Computerized system validation.
- SOP - Backup and restoration of electronic data.
- SOP - Cleaning and operation of Rapid mixer granulator

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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.

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.

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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.

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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 Pre-Risk Assessment as per FMEA:

Name of facility/Utility/Equipment/Process/Operation: Risk assessment study for impeller end point current min.& max. Parameter shift from recipe parameter to machine parameter in equipment.

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.	Batch reports verification	Batch report can print parameters which are removed	7	Flawed installation of software.	4	Procedure for batch report verification is in place during CSV of computerized system as per SOP	3	**84**	Low	Batch reports shall be verified during qualification and CSV activity as per SOP	Prd./Engg/ QA/IT						
2.	Communication failure verification of parameters	Operation & product failure.	5	Communication failure study not considered in qualification.	4	Communication failure study procedure is in place in CSV activity to verify any abnormal changes in parameters during communication lost.	3	**60**	Low	Communication failure study shall be performed during qualification and CSV activity.	Prd./Engg/ QA/IT						

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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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.	Power failure verification of IPC	Operation & product failure	5	Power failure study not verified	4	Power failure study procedure is in place to verify any abnormal changes in parameters during power cut off.	**5**	**100**	Low	Power failure study shall be performed during addendum CSV.	Prd./IT/ Engg./QA						
4.	Parameter Visibility	Failure in equipment performance or efficiency.	5	Operating sequence verification of equipment during qualification may not carry out.	4	1. Procedure for components verification and operating sequence is in place as per respective SOP which mitigates the potential cause of identified risk. 2.Procedure for software verification of PLC and IPC based computerized system is in place as per SOP (computerized system validation)	**5**	**100**	**Low**	Addendum CSV of RMG shall be carried for impacted functionality out as per SOP. - Addendum OQ of equipment shall be performed as per SOP.	Prd./IT/ Engg./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
5.	Controlling by PLC	Equipment failure	5	1. IPC software malfunctioning. 2. Communication Failure	4	1. Verification procedure for key functionality of control panel or IPC software is available as per SOP. 2. Controlling parameter verification procedure available.	**5**	**100**	Low	Key functionality of control panel shall be verified during OQ of equipment and controlled parameter operation shall be verified during qualification.	Prd./IT/ Engg./QA						
6.	Screen verification	Operation & product failure	5	Screen of IPC not verified during qualification	4	Screen verification procedure is available as per SOP.	**5**	**100**	Low	Screen verification test shall be done during computer system validation as per SOP	Prd./IT/ Engg./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
7.	Operation of machine	Impact on operational SOP	3	SOP / Manual/ test /certificate is not available.	4	This is GMP and GDP requirement & procedure is available for verification of documents as per SOP.	4	**48**	Low	SOP shall be revised according to the changes in system. Verification of documents shall be carried out during qualification as per SOP.	Prd./IT/ Engg./QA						

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13.0 Risk Control Measures:

Investigation/Finding:

Risk assessment study for risk assessment study for impeller end point current min.& max. parameter shift from recipe parameter to machine parameter in equipment with current process control and recommended actions.

Corrective Action:

CAPA No.PR Initiated for risk assessment study of impeller end point current min.& max. Parameter shift from recipe parameter to machine parameter in equipment.

14.0 Summary & Conclusion Report for Risk Assessment:

Summary:

During risk assessment study various potential failure mode derived and evaluated followed by potential failure effects and potential causes

S.No.	Proposed Action	Responsible Department	TCD
1.	Batch reports shall be verified during qualification and CSV activity as per SOP.	Prd/Engg/IT/QA	
2.	Communication failure study shall be performed during qualification and CSV activity.	Prd/Engg/IT/QA	
3.	Power failure study shall be performed during addendum CSV.	Prd/Engg/IT/QA	
4.	Addendum CSV of RMG shall be carried for impacted functionality out as per SOP No. Addendum OQ of equipment shall be performed as per SOP.	Prd/Engg/IT/QA	
5.	Key functionality of control panel shall be verified during OQ of equipment and controlled parameter operation shall be verified during qualification	Prd/Engg/IT/QA	
6.	Screen verification test shall be done during computer system validation as per SOP.	Prd/Engg/IT/QA	
7.	SOP shall be revised according to the changes in system. Verification of documents shall be carried out during qualification as per SOP.	Prd/Engg/IT/QA	

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 low and detailed risk assessment has been carried out and shall be attached during risk summarization.

15.1 Risk related to: Equipment

15.2 Risk categorization comments:

Risk is considered low for impeller end point current min.& max. parameter shift from recipe parameter to machine parameter in equipment.

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16.0 Final Report Approval (Pre Assessment):

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 Operations**			
	Head QA			

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17.0 Final Report Approval (Post Assessment):

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	Responsibility	Name	Signature	Date
Prepared by	**Engineering**			
Reviewed By	**Engineering**			
	Production			
	IT			
	Quality Assurance			
Approved By	**Head Operations**			
	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. IT

19.0 Abbreviation:

SOP : Standard Operating Procedure

FMEA : Failure Mode Effect Analysis

QRM : Quality Risk Management

QMS : Quality Management System

RPN : Risk Priority Number

RAS : Risk Assessment Study