RISK ASSESSMENT FOR REPLACEMENT OF ARM ASSEMBLY WITH NEW SCISSOR TYPE ARM ASSEMBLY OF BIN BLENDER

RISK ASSESSMENT STUDY

(FMEA ANALYSIS)

FOR

REPLACEMENT OF ARM ASSEMBLY WITH NEW SCISSOR TYPE ARM ASSEMBLY OF BIN BLENDER

Document No.:

Effective From/Approval Date: ……

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1.0 Quality risk assessment team:

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.

On dated …… breakdown intimation was initiated by production department for Bin blender not working up to mark and Bumping problem observed. During utility evaluation it was observed that arm assembly of Bin Blender needs to be replaced with scissor type arm assembly for permanent solution of the observed breakdown.

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 replacement of arm assembly of Bin Blender installed in facility.

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 Q9 for replacement of arm assembly of Bin Blender.

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 Q9 for replacement of arm assembly with new scissor type arm assembly of bin blender 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:

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.

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.

7.0 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- PM of bin Blender.
- SOP- Operation & Cleaning of Bin blender

8.0 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 Bin blender not working up to mark with Bumping problem observed. During utility evaluation it was observed that arm assembly of Bin Blender needs to be replaced with scissor type arm assembly for permanent solution of the observed breakdown. 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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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 Certain	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.

Detection	Scale	Parameter
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 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**	**Actions taken**	**Severity**	**Occurrence**	**Detection**	**New RPN**	**Risk Classification**
1.	Rusting/ Degradation of new Arm Assembly	Product failure	5	1. Due to low grade MOC. 2. Improper handling of equipment.	4	1. MOC certificate verified during installation as per sop of qualification SOP. 2. Procedure for operation and cleaning of Bin blender is available as per SOP.	4	**80**	Low	NA	NA	NA	NA	NA	NA	NA	NA
2.	Cross Contamination may occur	Product Failure	5	Lack of cleaning procedure for new scissor type arm assembly.	5	SOP for cleaning and operation of bin blender is available as per SOP.	3	**75**	Low	NA	NA	NA	NA	NA	NA	NA	NA
3.	Documentation	Failure of GMP requirements	5	Lack of supporting documents	4	Verification of Installation is carried out as per sop of qualification SOP No. SOP/BA/QAD/038.	4	**80**	Low	NA	NA	NA	NA	NA	NA	NA	NA
4.	Compatibility with Bin blender	Equipment performance	5	1. Installation of new Scissor type arm assembly may not done properly. 2. Required Utility may not provide.	4	Verification of Installation is carried out as per sop of qualification SOP No. SOP/BA/QAD/038.	4	**80**	Low	NA	NA	NA	NA	NA	NA	NA	NA
5.	Alignment of Arm Assembly	Operation failure	5	Alignment of arm assembly may not done properly.	5	Installation of arm assembly is carried out by qualified person.	3	**75**	Low	NA	NA	NA	NA	NA	NA	NA	NA
6.	Blender may fall during operation	Product failure	5	Size/ Dimension of new scissor type arm assembly may not suitable.	4	Qualification procedure and other required documents (Arm assembly drawing with proposed dimension) are available as a current control measure	4	**80**	Low	NA	NA	NA	NA	NA	NA	NA	NA

12.0 Risk Control Measures:

Investigation / Findings:

Proposal of replacement of existing arm assembly with new scissor type arm assembly for bin blender equipped in blending area-III, as per change control No……... Existing current control process is in place which mitigates the risk associated w.r.t. replacement of arm assembly of bin blender in blending area.

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 i.e. replacement of existing arm assembly with new scissor type arm assembly for bin blender equipped in blending area.

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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14.0 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**			

15.0 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			
	Quality Assurance			
	Head - Operation			
Approved by	**Head - QA**			

16.0 Risk Communication

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

1. Quality Assurance.
2. Production
3. Engineering

17.0 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