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

IPC SOFTWARE TO BE UPDATED TO PROVIDE THE PROVISION FOR TWO STAGE BLENDING IN EQUIPMENT

Document No.:

Effective From/Approval Date: ……

Risk Review Due on: …….

Remarks:

RISK ASSESSMENT STUDY FOR IPC SOFTWARE TO BE UPDATED TO PROVIDE THE PROVISION FOR TWO STAGE BLENDING IN EQUIPMENT

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 manufacturing facility is a tablets, capsule and oral liquid producing facility, 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 to update the IPC software to provide the provision for multiple blending stages (i.e. In addition to Batch No. stage to be incorporated.) in bin blender at blending 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 updation of IPC software to provide the provision of multiple stage blending in bin blender at blending 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 IPC software updating to provide the provision of two stages blending in bin blender in bin blender at blending area.
- ☞ 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 Bin blender
- SOP- Computerized system validation.
- SOP- Backup and restoration of electronic data.
- SOP- Cleaning and operation of Bin blender capacity

9.0 Background:

After completion of lubrication process of batch number it was observed that checking by and verifying by option not shown in IPC and due to this print not generated without verifying the recipe. Immediately inform to utility department through breakdown maintenance intimation request and event PR was initiated. After that utility department evaluated the problem and recommended to handover the machine online to the vendor for rectification. Further activity carried out by vendor and as per vendor it is observed from audit trial that the operator had pressed OK button without pressing ENTER button after entry of Batch Number. So duplicate

batch number was accepted, and SCADA was not allowing for checking and batch verification for that batch. For such duplication action interlock added on OK button in batch parameters screen so that this case will not happen again. As per Vendor justification there is no change in the display of any screen. While carrying out any modification/rectification in PLC/SCADA software, taken all the precaution so that the other parts of the existing developed software are not affected. So requalification of system may not need with respect to this updation. Further product having multiple blending option i.e. slugging and compaction batches shall not process in blending-I (due to chances of generation of duplicate batch number) till the change in the IPC system. These products will not run on this equipment till the updation of the blender IPC as per defined procedure. Further print out of Batch viewed by admin and printed, checked and verified by manually instead of electronic review as per defined level in IPC and same is attached with BMR.As a preventive action CAPA PR assigned to production for Updation of IPC program to provide multiple blending stage option.

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 IPC software update to provide the provision for two stage blending

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.	Audit trail reports, batch reports verification	Audit trial of batch may not generated	5	Software may not compatible with IPC and PLC to generate audit trial	5	Procedure for audit trial verification is in place during qualification and CSV of computerized system as per SOP	3	**75**	Low	Audit trial, batch reports shall be verified during qualification and CSV activity as per SOP	Prd./Engg/ QA/IT						
2.	Communication failure verification of IPC	Operation & product failure	5	Communication failure study not considered in qualification.	4	1. Communication failure study procedure is in place in CSV activity to verify any abnormal changes in recipe during communication lost. 2. Control loop test or recipe verification is a part of qualification procedure.	3	**60**	Low	Communication failure study shall be performed during qualification and CSV activity.	Prd./Engg/ QA/IT						
3.	Duplicate batch number can be accepted by system	1)Failure in Reports tracking 2) Duplicate batch can be manufactured	5	1) Due to improper software design 2) Due to software malfunction	4	1) For such duplication action as per Event number 126451 interlock added on OK button in batch parameters screen so that this case will not happen. 2)Duplicate batch number verification process procedure is in place as per SOP	**5**	**100**	**Low**	As per CAPA number –PR, IPC software should be update for multiple stage blending and Addendum CSV for impacted functionality shall be carried out 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
4.	Parameter Visibility	Failure in equipment performance or efficiency.	5	1. Operating sequence verification of equipment during qualification may not carry out. 2. Communication error from field instrument.	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 blender shall be carried for impacted functionality out as per SOP. - Addendum OQ of equipment shall be performed as per SOP.	Prd./IT/ Engg./QA						
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.	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 recipe during power cut off. System is connected to UPS.	**5**	**100**	Low	Power failure study shall be performed during addendum CSV UPS connectivity verification shall be performed in equipment qualification.	Prd./IT/ Engg./QA						
7.	Screen verification	Operation & product failure	5	Screen of IPC not verified	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						
8.	Documentation	Failure of GMP requirement Operation failure	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 to incorporate the procedure for multiple blending options. 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 IPC software updation for multiple stages blending in Bin blender is reviewed with current process control and recommended actions.

Corrective Action:

CAPAC Initiated for IPC software update to provide the provision for multiple stage blending.

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.	Addendum CSV of IPC shall be carried out as per SOP.	Prd/Engg/IT/QA	
2.	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	
3.	Power failure study shall be performed during addendum CSV.	Prd/Engg/IT/QA	
4.	SOP shall be revised to incorporate the procedure for multiple blending options. Document Verification shall be carried out during qualification as per SOP.	Production	

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 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 IPC software update to provide the provision for two stage blending.

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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