RISK ASSESSMENT STUDY

(FMEA ANALYSIS)

FOR

UPGRADATION OF FBP MACHINE SOFTWARE

Document No.: ……

Effective From/Approval Date: ……

RISK ASSESSMENT FOR UPGRADATION OF FBP MACHINE SOFTWARE

1.0 Table of contents:

RISK ASSESSMENT FOR UPGRADATION OF FBP MACHINE SOFTWARE

2.0 Quality risk assessment team:

S.No.	Team Member	Department	Designation	Sign/Date

HOD Approval

Name	Department	Designation	Sign & Date

RISK ASSESSMENT FOR UPGRADATION OF FBP MACHINE SOFTWARE

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 up-gradation of software of FBP machine having equipment ID installed 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 up-gradation of software of FBP machine having equipment ID in block facility to evaluate the mitigation & acceptance risk associated with it.

RISK ASSESSMENT FOR UPGRADATION OF FBP MACHINE SOFTWARE

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 Q9 for up-gradation of software of FBP machine having equipment ID in block 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.

RISK ASSESSMENT FOR UPGRADATION OF FBP MACHINE SOFTWARE

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 preparation and review of quality risk assessment procedure and its execution.

Information Technology Department is responsible for review of quality risk assessment 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 adequacy of quality risk assessment and approve the final decision taken after recommended action plan.

Quality Assurance Head 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 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- Preventive maintenance of Fluid bed processor.
- SOP- Operation & Cleaning Procedure of Fluid bed processor.
- SOP- Performing of equipment validation (equipment qualification)

RISK ASSESSMENT FOR UPGRADATION OF FBP MACHINE SOFTWARE

9.0 Background:

The facility is producing various ranges of tablets, capsules and oral liquid with the help of required utilities & machineries. Change control no. …….. initiated for software up-gradation of FBP machine having ID for creation of five level user group and activity performed by vendor by taking machine online and he observed that due to older version installed in FBP machine five level user group cannot be create and he recommends to upgrade the software version. 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.

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 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	9	Very remote chance design control will detect potential cause. Detection tools most likely will not detect failure.

Detection	Scale	Parameter
Remote		
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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RISK ASSESSMENT FOR UPGRADATION OF FBP MACHINE SOFTWARE

12.0 Risk Assessment as per FMEA:

Name of facility/Utility/Equipment/Process/Operation: Up-gradation of software of FBP

												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 (target date)**	**Actions taken**	**Severity**	**Occurrence**	**Detection**	**New RPN**	**Risk Classification**
1.	Compatibility of PLC with new software of equipment.	Equipment performance	5	1. Software may not compatible with PLC system. 2. Ethernet and serial communication with current system may not done. Installation of new software may not done properly.	4	Procedure for verification of software, equipment component as well as communication detail during qualification of equipment is available as per SOP which mitigates potential cause of indicated risk.	4	80	Low	CSV of new software shall be carried out as per SOP including the test as interlocking, boundary range, access right etc.	Prd./Engg./QA/IT						
2.	Previous batch reports may be lost	Failure in tracking of data.	7	Tracking of data related to alteration i.e. changes in process parameter access level (who and when the changes done) And deletion of data is not available which leads to lack of GMP and GxP requirements	5	1. Currently provision is available for attachment report with respective BMR for record . 2. For backup and data restoration procedure is in place as per SOP (Backup and restoration procedure of electronic data) 3.Before software up-gradation previous data backup is available as per SOP (Backup and restoration procedure of electronic data)	4	**140**	Medium	Data should be save on another standalone system with previous software and validation of that system shall be done. If standalone system got damaged or did not perform normally then another standalone system shall be installed with the help of vendor and same standalone system shall be validated, backup of data shall be migrated to new validated standalone system. It is one time activity and change control no. …... is already in place. Activity shall be carried out by separate action item of change control no. …….	Prd./Engg./QA/IT						

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RISK ASSESSMENT FOR UPGRADATION OF FBP MACHINE SOFTWARE

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3.	Parameter Visibility	Failure in equipment performance or efficiency.	5	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	1.Procedure for components verification and operating sequence is in place as per respective SOP which mitigate the potential cause of identified risk. 2.Procedure for verification of PLC and IPC based computerized system is in place as per SOP (computerized system validation)	3	**60**	Low	Operating sequence, boundary range and access level shall be verified during equipment qualification and CSV.	Prd./Engg./QA/IT						
5.	Controlling by PLC	Equipment failure	5	1. IPC software malfunctioning. 2. Communication Failure	5	1. Verification procedure for key functionality of control panel or IPC software is available as per SOP 2. Controlling parameter verification procedure available.	3	**75**	Low	Key functionality of control panel shall be verified during OQ activity and controlled parameter operation shall be verified during qualification.	Prd./Engg./QA/IT						
6.	Power failure verification of IPC with new software	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.	4	**80**	Low	Power failure study shall be performed during qualification of equipment and CSV.	Prd./Engg./QA/IT						
7.	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 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						

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RISK ASSESSMENT FOR UPGRADATION OF FBP MACHINE SOFTWARE

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8.	Individual login	Product failure	5	New software may not support for individual login.	4	1. Individual login are provided for different users. 2. Procedure for individual login available with IPC and procedure for verification of user level privilege is in place as per SOP.	4	**80**	Low	Compatibility of individual login shall be verified during qualification and CSV.	Prd./Engg./QA/IT						
9.	Failure in Function of IPC	Operation failure	5	1. Malfunctioning of PLC with respect to IPC with new software 2. Printout of recipe not matched with commanded input.	4	1. Boundary test procedure of specific parameter is in place during csv as per SOP. 2. SOP is in place for equipment qualification. 3. Verification procedure of print out with respect to decided recipe is in place during qualification. 4. Operational sequence verification procedure available during qualification of equipment.	4	**80**	Low	Qualification of new software shall be carried out as per SOP.	Prd./Engg./QA/IT						
10.	Unique User ID and Password	Product failure	5	Nonfunctioning of unique user ID feature may result into access of unauthorized user to the system due to common ID and password.	4	1. Procedure in place for verification of unique user ID during csv as per SOP. 2. Documented procedure available (“User management and password policy”) for ID/Password creation and granting access to the users.	4	80	Low	1. Unique user ID shall be created for all individual users and that shall be used during operation of equipment. 2. Unique user id verification shall be performed during qualification for in line with SOP.	Prd./Engg./QA/IT						

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RISK ASSESSMENT FOR UPGRADATION OF FBP MACHINE SOFTWARE

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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 (target date)**	**Actions taken**	**Severity**	**Occurrence**	**Detection**	**New RPN**	**Risk Classification**
11.	Audit trail	Audit trial of batch may not generated	5	New software may not compatible with IPC and PLC to generate audit trial	5	Procedure for audit trial verification is in place during qualification of equipment as per SOP.	3	**75**	Low	Audit trial shall be verified during qualification as per SOP and CSV activity as per SOP	Prd./Engg./QA/IT						
12.	Password – aging (expiry) facility	Keeping same password for long period of time increases risk of password breach by unauthorized user.	5	Due to lack of procedures for management of password	4	Procedure is available for verification of password –aging (expiry) feature as per SOP "Computerized System Validation".	4	**80**	Low	For Equipment, password – aging (expiry) feature and CSV for this feature shall be performed as per SOP "Computerized System Validation".	Prd./Engg./QA/IT						
13	Data backup and restoration	Electronic data shall be backed up from the system, but it may not be able to restore, which leads to non-retrieval of data	5	New software may not compatible with IPC and PLC for data backup and restoration.	4	1.SOP "Backup and restoration procedure for electronic data" is in place. 2.Verification procedure of system software for performing data backup and restoration is available to mitigate the possible risk.	3	**60**	Low	Data backup and restoration test should be performed and verified during CSV activity.	Prd./Engg./QA/IT TCD:						

13.0 Risk Control Measures:

Investigation / Findings:

- Software of Fluidized Bed Processor machine shall be upgraded.

Corrective Action:

- Change Control initiated for the up-gradation of software of Fluid Bed Processor machine and same shall be validated as per SOP.

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14.0 Summary & Conclusion Report for Risk Assessment:

Summary:

Available control measures are sufficient to mitigate the risk of contamination and cross contamination. However, for further mitigation of risk below are the recommended actions.

S. No.	Proposed Action	Responsible Department	TCD
1.	Qualification of new software shall be carried out as per SOP and CSV as per SOP.	Engineering / Production/ Quality Assurance /IT	
2.	Operating sequence, boundary range and access level shall be verified during equipment qualification.		
3.	Key functionality of control panel and controlling parameter functioning shall be verified during qualification of equipment.		
4.	Power failure study shall be performed during computerized system validation.		
5.	Communication failure study shall be performed during computerized system validation.		
6.	Audit trial shall be verified during csv/qualification.		
7.	Compatibility of individual login shall be verified during computerized system validation.		
8.	1. Unique user ID shall be created for all individual users and that shall be used during operation of FBP machine. 2. Unique user id verification shall be performed during qualification for FBP in line with SOP		
9.	For Equipment, password – aging (expiry) feature and CSV for this feature shall be performed as per SOP “Computerized System Validation”.		
10.	Data backup and restoration test should be done during CSV activity.		

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 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			
	QA			
Approved by	**Head - Operation**			
	Head - QA			

16.0 Final Report Approval (Post Assessment):

The final report shall be signed after implementing all the recommended actions and based on the implementation of actions, reclassification of risk was completed. All the reports or documents have been attached to the respective report (if applicable).

Signature in the block below indicates. 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			
	QA			
Approved by	**Head - Operation**			
	Head - QA			

17.0 Risk Communication:

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

1. Quality Assurance.
2. Production
3. Engineering
4. Information technology

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