RISK ASSESSMENT STUDY

FMEA ANALYSIS

FORREPLACEMENT OF FBP HARD DISK

WITH HDD/SSD

RISK ASSESSMENT STUDY FOR REPLACEMENT OF FBP HARD DISK WITH HDD/SSD

Table of contents

1.0 Quality risk management team:

RISK ASSESSMENT STUDY FOR REPLACEMENT OF FBP HARD DISK WITH HDD/SSD

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

2.0 Introduction:

RISK ASSESSMENT STUDY FOR REPLACEMENT OF FBP HARD DISK WITH HDD/SSD

The manufacturing facility is a tablet, capsule and oral liquid producing facility, the facility is producing various ranges of tablets; capsules and oral liquid with the help of required utility & equipment's.

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 for replacement of FBP hard disk with HDD/SSD having Equipment 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 replacement of hard disk of FBP with HDD/SSD having equipment in facility.

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 ICH Q9 for replacement of FBP hard disk with HDD/SSD having equipment 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.
- ☞ The following process /steps have been/ will be followed for risk assessment.

RISK ASSESSMENT STUDY FOR REPLACEMENT OF FBP HARD DISK WITH HDD/SSD

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 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 Operations 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.

7.0 Reference Documents:

The relevant Document for monitoring, control is listed below:-

- SOP- Handling of Corrective Action & Preventive actions.
- SOP- Change management system
- SOP- Event management
- SOP- Quality Risk management.
- SOP- Preventive maintenance of Fluid bed processor.
- SOP- Performing of equipment validation (equipment qualification)
- SOP- Operation & Cleaning Procedure of Fluid bed processor.
- SOP - Computerized system validation.
- SOP - Backup and restoration of electronic data
- SOP - User Management and Password Policy

8.0 Background:

Breakdown intimation initiated on dated 16/06/23 at 14:55 in FBP for no occurrence of user id along with date & time. During evaluation by IT department it was observed that Hard disk drive of IPC is corrupted and need to replace with new one. Further discussion done with vendor telephonically and he recommends to sent IPC for rectification. IPC is sent to Vendor for repairing. As per Vendor the Hard disk of IPC of FBP not working and required to replace with advance version SSD disc with same capacity i.e. 500 GB. The SSD (solid state drive) is advance version to HDD drive. PR is initiated for the same. 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.

RISK ASSESSMENT STUDY FOR REPLACEMENT OF FBP HARD DISK WITH HDD/SSD

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 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)

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.
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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RISK ASSESSMENT STUDY FOR REPLACEMENT OF FBP HARD DISK WITH HDD/SSD

11.0 RISK ASSESSMENT AS PER FMEA:-

Name of facility/Utility/Equipment/Process/Operation: **Replacement of FBP hard disk with HDD/SSD**

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 installation may not be done properly in new SSD.	Equipment performance	5	1. Software may not compatible with new SSD of system. 2. Ethernet and serial communication with current system may not be done. Installation of software may not be done properly in new	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 software shall be carried out as per SOP.	Prod./Engg						
2.	Previous batch reports may be lost	Existing data may not be available. Reports data cannot be track.	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	3	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 installation previous data backup is available as per SOP (Backup and restoration procedure of electronic data)	4	84	Low	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. PR is already in place. Activity shall be carried out by separate action item of change control.	Prod./Engg						

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RISK ASSESSMENT STUDY FOR REPLACEMENT OF FBP HARD DISK WITH HDD/SSD

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.	Set parameter not set as required.	Failure in equipment performance or efficiency.	5	1. Operating sequence verification of equipment during qualification may not carried out. 2. Software 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.						
4.	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						
5.	Power failure verification of IPC with 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						
6.	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./						
7.	Individual login	Product failure	5	Software installed in HDD/SSD 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/						

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RISK ASSESSMENT STUDY FOR REPLACEMENT OF FBP HARD DISK WITH HDD/SSD

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.	Failure in Function of IPC	Operation failure	5	1. Malfunctioning of PLC with respect to IPC with new software installed in new HDD/SSD 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.						
9.	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						
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 verification shall be performed during qualification for FBP in line with SOP.	Prd./Engg./						

RISK ASSESSMENT STUDY FOR REPLACEMENT OF FBP HARD DISK WITH HDD/SSD

12.0 Risk Control Measures:

Investigation/Findings:

- Breakdown intimation initiated in FBP for no occurrence of user id along with date & time. During evaluation by IT department it was observed that Hard disk drive of IPC is corrupted and need to replace with new one. Further discussion done with vendor telephonically and he proposed to change the hard disk with advance version SSD disc.

- **Corrective Action:** Change Control initiated for replacement of FBP hard disk with new HDD/SSD having equipment and same shall be validated as per SOP.

13.0 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.	CSV of new software shall be carried out as per SOP including the test as interlocking, boundary range, access right etc.		
2.	Operating sequence, boundary range and access level shall be verified during equipment qualification and CSV.		
3.	Key functionality of control panel shall be verified during OQ activity and controlled parameter operation shall be verified during qualification.		
4.	Power failure study shall be performed during qualification of equipment and CSV.		
5.	Communication failure study shall be performed during qualification and CSV activity.		
6.	Compatibility of individual login shall be verified during qualification and CSV		
7.	Audit trial shall be verified during qualification as per SOP and CSV activity as per SOP.		
8.	Unique user id verification shall be performed during qualification for FBP in line with SOP.		
9.	For Equipment FBP, 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 performed and verified 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.

14.0 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 shall be carried out and attached during risk summarization.

RISK ASSESSMENT STUDY FOR REPLACEMENT OF FBP HARD DISK WITH HDD/SSD

14.1 Risk related to: Equipment

14.2 Risk categorization comments:

Change is related to replacement of FBP hard disk with HDD/SSD having Equipment ID.

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

RISK ASSESSMENT STUDY FOR REPLACEMENT OF FBP HARD DISK WITH HDD/SSD

16.0 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			

17.0 Risk Communication:

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

1. Quality Assurance.
2. Engineering
3. Production
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
HMI : Human Machine Interface