RISK ASSESSMENT FOR IPC IN COMPRESSION MACHINE (73 STATION)

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

REPLACEMENT OF IPC IN COMPRESSION MACHINE 73 STATION

Document No.: ……

Effective From/Approval Date: ……

Risk Review Due on: …….

Remarks: Risk assessment is prepared based on Change control. The changes for replacement of IPC in compression m/c 73 St. shall be done through change control

RISK ASSESSMENT FOR IPC IN COMPRESSION MACHINE (73 STATION)

1.0 Table of contents:

RISK ASSESSMENT FOR IPC IN COMPRESSION MACHINE (73 STATION)

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**

RISK ASSESSMENT FOR IPC IN COMPRESSION MACHINE (73 STATION)

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 against reported breakdown as per request No……. In view of proposal for replacement of IPC in compression M/c 73 station, risk assessment study shall be performed at G block, 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 replacement of IPC in compression M/c 73 station 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 replacement of IPC in compression M/c 73 station at G block.
- 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.

RISK ASSESSMENT FOR IPC IN COMPRESSION MACHINE (73 STATION)

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 - Calibration Policy
- SOP - Change management system
- SOP - Event management
- SOP - Handling of corrective and preventive actions
- SOP - Qualification of Equipment, Facility, Utilities and System
- SOP - Handling of OOS/OOT/Atypical investigations
- SOP - Preventive maintenance of tablet compression M/c
- SOP - Computerized system validation.
- SOP - Backup and restoration of electronic data.

RISK ASSESSMENT FOR IPC IN COMPRESSION MACHINE (73 STATION)

9.0 Background:

On dated …… breakdown intimation request intimation no…….. was observed for frequently hanging of IPC. Utility has checked the electrical connection of IPC and found ok. Further the problem is discussed with service engineer and he visited the site on dated …….., and found that IPC hardware has some problem and not working effectively and need to send for repairing as it was not repair at site. Meanwhile a compression M/c 49 station of same Make- Sejong is available at site. The machine has inbuilt IPC of same specification as of Compression M/c 73 station (Make Sejong).

Hence it was decided to replace IPC of Compression M/c 73 station (Make Sejong) with IPC of compression M/c 49 station which was discontinued as per PR. Equivalency for IPC is attached as per Attachment-I

Risk assessment study for replacement of IPC of compression m/c 73 station Make Sejong at G block, in line with the guidance of the Risk Management of Macleod's and ICH Q9.

Data backup of compression machine 49 station shall be taken in any backup media and same shall be archive in QA department. In case of any data requirement for the data of archived media shall be restored on any PC and use for reference purpose only.

RISK ASSESSMENT FOR IPC IN COMPRESSION MACHINE (73 STATION)

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 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.

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

RISK ASSESSMENT FOR IPC IN COMPRESSION MACHINE (73 STATION)

12.0 Pre-Risk Assessment as per FMEA:

Name of facility/Utility/Equipment/Process/Operation: Risk assessment study for Replacement of IPC in compression Machine 73 station

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.	- Improper Installation of New IPC	- Impact on Equipment performance -Operation failure -IPC may not be used for operation purpose. -IPC may be crashed /hang during operation.	5 (Performance moderately affected	1. IPC Software may not compatible with PLC system. 2. Ethernet and serial communication with New IPC may not compatible with existing system. 3. Installation of new IPC may not do properly. 4. Compression machine may not support installation of new IPC due to Improper hardware/ Software configuration. 5. Person may not be trained for installation of IPC.	4 (Few failure likely)	1) SOP (Computerized system validation) is in place for qualification/ validation of equipment/ instrument. 2) Installation of IPC will be performed by trained vendor. 3) Attachment -I is available equivalency of IPC.	**5 (**Moderately high chance	**100**	**Low**	CSV of new IPC shall be carried out as per SOP.	Prd./IT/Engg./QA						

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RISK ASSESSMENT FOR IPC IN COMPRESSION MACHINE (73 STATION)

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
2.	Improper Data Backup and Data Migration from Existing IPC to new IPC	-Data may be loss due to Improper data migration from Existing IPC to newly installed IPC -Data may not be available for review and operational use.	5(Performance moderately affected	1. Data of existing IPC may not be compatible with newly installed IPC 3. Existing IPC data backup may not be available.	4(Few failure likely)	1. SOP (Computerized system validation) is in place for qualification/ validation of equipment/ instrument. 2. SOP (Backup and restoration of electronic data) is in place for data backup. 3. Data of existing IPC is backup as per SOP on daily and monthly tape and already available with site QA and remote location.	**5**(Moderately high chance	**100**	**Low**	Existing data from existing IPC shall be migrated to new IPC by vendor with the help of IT as per service report which shall be provided by vendor.	VQ,ggrE/IT/Prd						

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RISK ASSESSMENT FOR IPC IN COMPRESSION MACHINE (73 STATION)

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												Actions taken	SEV (S)/ REMARKS	OCC (O) / REMARKS	DET (D) / REMARKS	New RPN	Risk Classification
3.	-Impact on existing PLC of compression M/c due to installation of new IPC.	- Impact on Equipment performance Operation failure	5(Performance moderately affected	1. IPC Software may not compatible with PLC system. 2. Ethernet and serial communication with current system may not compatible with existing system. Installation of new software may not done properly. 3.SCADA system may not work with PLC.	4(Few failure likely).	Procedure for verification of software, equipment component as well as communication detail during qualification of equipment is available as per SOP which mitigate potential cause of indicated risk There is no change in PLC software program. More over PLC software is already qualified as per SOP as per PLC protocol.	5(Moderately high chance	**100**	**Low**	CSV of new IPC shall be carried out as per SOP.	Prd./IT/Engg./QA						
4.	Parameter Visibility	Failure in equipment performance or efficiency.	5(Performance moderately affected	1. Operating sequence verification of equipment during qualification may not carry out. 2. Software version may not compatible with existing system. 3. Communication error from field instrument.	4/ Few failure likely	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) 3. Filed instrument calibration sop should be available.	5(Moderately high chance	**100**	**Low**	- CSV of new IPC shall be carried out as per SOP. - Addendum OQ of equipment shall be performed as per SOP.	Prd./IT/Engg./QA						

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RISK ASSESSMENT FOR IPC IN COMPRESSION MACHINE (73 STATION)

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												Actions taken	SEV (S)/ REMARKS	OCC (O) / REMARKS	DET (D) / REMARKS	New RPN	Risk Classification
5.	Controlling by PLC	Equipment failure	5(Performance moderately affected	-1. IPC software malfunctioning. 2. Communication Failure	4/ Few failure likely	-1. Verification procedure for key functionality of control panel or IPC software is available as per SOP 2. Controlling parameter verification procedure available.	5(Moderately high chance	**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(Performance moderately affected	Power failure study not verified	4/ Few failure likely	Power failure study procedure is in place to verify any abnormal changes in recipe during power cut off. System is connected to UPS.	5(Moderately high chance	**100**	Low	Power failure study shall be performed during CSV UPS connectivity verification shall be performed in equipment qualification.	Prd./IT/Engg./QA						

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RISK ASSESSMENT FOR IPC IN COMPRESSION MACHINE (73 STATION)

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												Actions taken	SEV (S)/ REMARKS	OCC (O) / REMARKS	DET (D) / REMARKS	New RPN	Risk Classification
7.	Audit trail	Audit trial of batch may not generated	5(Performance moderately	New IPC may not compatible to generate audit trial	4/ Few failure likely	Procedure for audit trial verification is in place during qualification of equipment as per SOP.	**5**(Moderately high chance.	**100**	Low	Audit trial shall be verified during qualification as per SOP.	Prd./IT/Engg./QA						
8.	Impact on Data backup of IPC of Discontinued Compression M/c	-Data may not be available for review. -Data backup may not be available.	5(Performance moderately	Data backup not done for IPC. Data may be loss due to data migration to IPC.	4/ Few failure likely	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.	**5**(Moderate chance design control will detect potential cause).	**100**	Low	Data backup for IPC of shall be done before migration of IPC data of and same shall be achieved in QA. .	Prd./IT/Engg./QA						

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RISK ASSESSMENT FOR IPC IN COMPRESSION MACHINE (73 STATION)

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
9.	Documentation	Failure of GMP requirement	3 (Slight effect on performance)	SOP/Manual/ test /certificate is not available	4 (Slight)	This is GMP and GDP requirement & procedure is available for verification of documents as per SOP.	4(design control will detect potential cause)	**48**	Low	Verification of documents shall be carried out during qualification as per SOP.	Prd./IT/Engg./QA						

RISK ASSESSMENT FOR IPC IN COMPRESSION MACHINE (73 STATION)

13.0 Risk Control Measures:

Investigation/Finding:

Risk assessment study for replacement of IPC in compression M/c 73 Station is reviewed with current process control and recommended actions.

Corrective Action:

PR initiated for replacement of IPC of same specification.

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.	CSV of new IPC shall be carried out as per SOP.	Prd/Engg/IT/QA	
2.	Existing data from existing IPC shall be migrated to new IPC vendor with the help of IT as per SOP.	Prd/Engg/IT/QA	
4.	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	
5.	Power failure study shall be performed CSV	Prd/Engg/IT/QA	
6.	UPS connectivity verification shall be performed in equipment qualification	Prd/Engg/IT/QA	
7.	Data backup for IPC shall be done before migration of IPC data and same shall be achieved in QA.	Prd/Engg/IT/QA	
8.	Document Verification 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.

RISK ASSESSMENT FOR IPC IN COMPRESSION MACHINE (73 STATION)

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 replacement of IPC in Compression machine 73 Station.

RISK ASSESSMENT FOR IPC IN COMPRESSION MACHINE (73 STATION)

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			

RISK ASSESSMENT FOR IPC IN COMPRESSION MACHINE (73 STATION)

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			

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