# RISK ASSESSMENT STUDY

# (FMEA ANALYSIS)

# FOR

# REPLACEMENT OF IPC WITH SPARE IPC IN COMPRESSION MACHINE

**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 machine shall be done through change control

# RISK ASSESSMENT FOR REPLACEMENT OF IPC WITH SPARE IPC IN COMPRESSION MACHINE

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## 1.0 Quality Risk Management Team:

# RISK ASSESSMENT FOR REPLACEMENT OF IPC WITH SPARE IPC IN COMPRESSION MACHINE

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 |
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| **HOD Approval** | | | | |
| **Name** | | **Department** | **Designation** | **Sign/Date** |
| | | | | |

# RISK ASSESSMENT FOR REPLACEMENT OF IPC WITH SPARE IPC IN COMPRESSION MACHINE

## 2.0 Introduction:

The facility is producing various ranges of tablets capsules and oral liquid with the help of require utility & equipment's.

## 3.0 Objective:

The objective of this protocol is to perform the Quality Risk assessment study against reported breakdown as per request. In view of proposal for replacement of IPC in compression M/c having equipment ID, risk assessment study shall be performed in line with the guidance of the Risk Management and ICH Q9.

## 4.0 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 as well as evaluates the mitigation & acceptance the risk associated with it.

## 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 safety of the patient.
- Various risks associated / anticipated shall be for replacement of IPC in compression machine having equipment ID……...
- Risk over the quality of products manufactured in the equipment shall be identified, analyzed and evaluated. Control measures shall be evaluated and risk shall be categorized based on calculated risk priority number.
- 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 risk assessment carried out.
- The control mechanism and the risk communication shall be enforced / verified in the operating documentation.

## 6.0 Responsibility:

# RISK ASSESSMENT FOR REPLACEMENT OF IPC WITH SPARE IPC IN COMPRESSION MACHINE

**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.

**Quality Assurance** is responsible for review of quality risk assessment and its execution.

**Head Quality Assurance/designee** is responsible for approval adequacy of quality risk assessment and approves the final decision taken after recommended action plan (if any).

**Head Operations** is responsible for approval adequacy of quality risk assessment.

## 7.0 Reference Documents:

The relevant SOP's & Document for monitoring, control are listed below:

- 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

## 8.0 Background:

On dated ……. breakdown intimation request intimation no…… received for decrease of main pressure of station-2 against set reference value in compression machine having equipment ID. As per utility evaluation it was observed that the IPC is hanged and as per vendor recommendation needs to be change. It is proposed to change the faulty IPC of compression machine having equipment ID with spare IPC of compression machine having equipment ID from compression area discontinued as per PR. IPC of machine is replaced with new IPC as per PR and old IPC is kept as a spare.

Risk assessment study for replacement of IPC of compression m/c having equipment ID at G block, in line with the guidance of the Risk Management and ICH Q9

## 9.0 Risk Ranking Parameters:

# RISK ASSESSMENT FOR REPLACEMENT OF IPC WITH SPARE IPC IN COMPRESSION MACHINE

## 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:

## RISK ASSESSMENT FOR REPLACEMENT OF IPC WITH SPARE IPC IN COMPRESSION MACHINE

| 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 1,1500,000). |
| Remote | 2 | Remote, rare number of historical failure (1 in 1,50,000). |
| Very slight | 3 | Very few failures likely (1 in 15,000) |
| Slight | 4 | Few failures 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 |

# RISK ASSESSMENT FOR REPLACEMENT OF IPC WITH SPARE IPC IN COMPRESSION MACHINE

## 11.0 Risk Assessment as per FMEA:

**Name of facility/Utility/Equipment/Process/Operation:** Risk assessment study for Replacement of IPC with spare IPC in compression Machine

| 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) | Action Results | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | Action taken | Severity | Occurrence | Detection | New RPN | Risk Classification |
| 1 | Improper Installation of New IPC | 1. Impact on equipment performance<br>2.Operation failure<br>3. IPC may not be used for operation purpose.<br>4. IPC may be crashed /hang during operation. | 7 | 1. IPC Software may not compatible with PLC system.<br>2. Ethernet and serial communication with new IPC may not compatible with existing system.<br>3.Installation of new IPC may not do properly.<br>4.Compression machine may not support installation of new IPC due to Improper hardware/ Software configuration.<br>5. Person may not be trained for installation of IPC. | 2 | 1.SOP (Computerized system validation) is in place for qualification/ validation of equipment/ instrument.<br>2. Installation of IPC will be performed by trained Person. | 4 | 56 | Low | Installation and Operation qualification of new IPC shall be carried out as per SOP. | IT/ENGG/ Production/QA | | | | | | |

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QUALITY ASSURANCE DEPARTMENT

# RISK ASSESSMENT FOR REPLACEMENT OF IPC WITH SPARE IPC IN COMPRESSION MACHINE

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | Action taken | Severity | Occurrence | Detection | New RPN | Risk Classification |
| 2. | Impact on existing PLC of compression M/c due to installation of new IPC. | 1.Impact on Equipment performance<br><br>2.Operation failure | 10 | 1. IPC Software may not compatible with PLC system.<br>2. Ethernet and serial communication with current system may not compatible with existing system.<br>3.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 mitigate potential cause of indicated risk. | 2 | 80 | Low | Installation and Operation qualification of new IPC shall be carried out as per SOP. | IT/ENGG./ Production/QA | | | | | | |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | Action taken | Severity | Occurrence | Detection | New RPN | Risk Classification |
| 3. | Improper Data Backup and Data Migration from Existing IPC to new IPC | 1.Data may be loss due to Improper data migration from Existing IPC to newly installed IPC<br><br>2.Data may not be available for review and operational use. | 8 | 1. Data of existing IPC may not be compatible with newly installed IPC<br><br>2. Existing IPC data backup may not be available. | 3 | 1.SOP (Computerized system validation) is in place for qualification/ validation of equipment/ instrument<br><br>2. Data of existing IPC is backup as per SOP on daily and monthly tape and already available with site QA and remote location. PR event has been taken for the data which is not recorded by the system due to hanging problem. | 2 | 48 | Low | Migration Qualification Shall be done as per SOP | IT/ENGG./ Production/QA | | | | | | |

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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) | Action Results | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | Action taken | Severity | Occurrence | Detection | New RPN | Risk Classification |
| 4. | Parameter Visibility | Failure in equipment performance or efficiency. | 7 | 1. Operating sequence verification of equipment during qualification may not carry out.<br><br>2. Software version may not compatible with existing system.<br><br>3.Communication error from field instrument. | 3 | 1. Procedure for components verification and operating sequence is in place as per respective SOP which mitigates the potential cause of identified risk.<br><br>2.Procedure for software verification of IPC based computerized system is in place as per SOP (computerized system validation)<br><br>3. Filed instrument calibration SOP is also available. | 3 | 63 | Low | 1. Operation Qualification Shall be done as per SOP.<br><br>2. OQ of equipment shall be performed as per SOP. | IT/ENGG./ Production/QA | | | | | | |

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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) | Action Results | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | Action taken | Severity | Occurrence | Detection | New RPN | Risk Classification |
| 5. | Controlling by PLC | Equipment failure | 10 | 1. IPC software malfunctioning.<br><br>2.Communication Failure | 5 | 1. Verification procedure for key functionality of control panel or IPC software is available as per SOP<br><br>2. Controlling parameter verification procedure available. | 2 | 100 | Low | Key functionality of control panel shall be verified during OQ of equipment and controlled parameter operation shall be verified during qualification. | IT/ENGG./ Production/QA | | | | | | |
| 6. | Power failure verification of IPC | Operation & product failure | 7 | Power failure study not verified | 3 | Power failure study procedure is in place to verify any abnormal changes in recipe during power cut off. System is connected to UPS. | 4 | 84 | Low | 1.Power failure study shall be performed during CSV as per SOP.<br><br>2. UPS connectivity verification shall be performed in equipment qualification. | IT/ENGG./ Production/QA | | | | | | |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | Action taken | Severity | Occurrence | Detection | New RPN | Risk Classification |
| 7. | Documentation | Failure of GMP requirement | 6 | SOP / Manual/ test /certificate is not available | 3 | This is GMP and GDP requirement & procedure is available for verification of documents as per SOP. | 3 | 54 | Low | Verification of documents shall be carried out during qualification as per SOP. | IT/ENGG./ Production/QA | | | | | | |
| 8. | Audit trail | Audit trial of batch may not generated | 8 | New IPC may not compatible to generate audit trial | 3 | Procedure for audit trial verification is in place during qualification of equipment as per SOP. | 2 | 48 | Low | Audit trial shall be verified during qualification as per SOP. | IT/ENGG./ Production/QA | | | | | | |
| 9. | Communication failure verification of IPC | Operation & product failure | 7 | Communication failure study not verified | 3 | Communication failure study procedure is in place to verify any abnormal changes in recipe during communication failure. | 4 | 84 | Low | Communication failure study shall be performed during CSVas per SOP. | IT/ENGG./ Production/QA | | | | | | |

# RISK ASSESSMENT FOR REPLACEMENT OF IPC WITH SPARE IPC IN COMPRESSION MACHINE

## 12.0 Risk Control Measures:

**Investigation / Findings:**

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

**Corrective Action:**

PR initiated for replacement of IPC of same specification.

## 13.0 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. | Installation and Operation qualification of new IPC shall be carried out as per SOP. | Prd/Engg/IT/QA | |
| 2. | Installation and Operation qualification of new IPC shall be carried out as per SOP. | Prd/Engg/IT/QA | |
| 3. | Migration Qualification Shall be done as per SOP. | Prd/Engg/IT/QA | |
| 4 | 1. Operation Qualification Shall be done as per SOP.<br>2. OQ of equipment shall be performed as per SOP | Prd/Engg/IT/QA | |
| 5. | 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 | |
| 6. | 1.Power failure study shall be performed during CSV as per SOP<br>2. UPS connectivity verification shall be performed in equipment qualification.in QA. | Prd/Engg/IT/QA | |
| 7. | Verification of documents shall be carried out during qualification as per SOP. | Prd/Engg/IT/QA | |
| 8. | Audit trial shall be verified during qualification as per SOP. | Prd/Engg/IT/QA | |
| 9. | Communication failure study shall be performed during CSV 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 REPLACEMENT OF IPC WITH SPARE IPC IN COMPRESSION MACHINE

## 14.0 Risk Categorization:

(Product, Process, Equipment, System, Cross Contamination, Data integrity, Quality System module (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.

**14.1 Risk related to:** Equipment

**14.2 Risk categorization comments:**

Risk is considered low for replacement of IPC in Compression machine.

## 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 are in place/identified, documented and have been reviewed and found to be acceptable.

| Responsibility | | Name | Signature | Date |
|---|---|---|---|---|
| **Prepared By** | **Engineering** | | | |
| | **Engineering** | | | |
| | **Production** | | | |
| | **Information Technology** | | | |
| | **Quality Assurance** | | | |
| **Approved By** | **Head Operations** | | | |
| | **Head QA** | | | |

# RISK ASSESSMENT FOR REPLACEMENT OF IPC WITH SPARE IPC IN COMPRESSION MACHINE

## 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** | | | |
| | **Information Technology** | | | |
| | **Quality Assurance** | | | |
| **Approved By** | **Head Operations** | | | |
| | **Head QA** | | | |

## 17.0 Risk Communication:

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

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

## 18.0 Abbreviation:

| | | |
|---|---|---|
| SOP | : | Standard Operating Procedure |
| FMEA | : | Failure Mode Effect Analysis |
| CFR | : | Code of Federal Regulation |
| QRM | : | Quality Risk Management |
| QMS | : | Quality Management System |
| RPN | : | Risk Priority Number |
| RAS | : | Risk Assessment |
| SME | : | Subject Matter Expert |