# Risk Assessment Document
# For
# Compressed Air System

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# RISK ASSESSMENT FOR COMPRESSED AIR SYSTEM

## 1 Introduction

According to the definition, given in Annex 15 to the EU-GMP-Guide, a Risk Assessment is a method to assess and characterize the critical parameters in the functionality of an equipment or process. Therefore, risk assessment is a key element in the qualification and validation approach.

In the project context, risk assessment for the equipment is performed as basic GMP/EHS-Risk Assessment, which shall help to identify important GMP/ EHS-requirements.

## 2 Aim of Risk Assessment

At the very basic stage of design the Risk Assessment is carried out to verify that all features are taken into consideration to avoid the risk of failure of critical GMP and EHS parameter in the equipment.

During study, all GMP, EHS and operational parameters will be identified and assessed for the risk, appropriate mitigation will be proposed and verification point will be identified and defined.

The Risk Assessment report is produced to provide the documented evidence that design concepts or requirement are complete in considering all GMP, EHS and operational risks.

## 3 Reference Documents/ Drawings

| S.No. | Document Title | Document Number |
|---|---|---|
| 1. | Validation master plan | |

## 4 Equipment/ System Description

This risk assessment is conducted for a Compressed Air System, which shall consist of the following main components:

- Air Compressor
- Cooling Unit
- Desiccant type heatless Dryer
- Receiver
- Compressed air distribution system
- End point filter cartridges (In manufacturing, filtration, washing, filling & sealing areas)

The Compressed Air System for this project has been designed for obtaining clean compressed air to be used for:

- Process aeration
- Pneumatic operation (valves, doors etc.)

Most of the possible risk concerning the handling/ operation of the Compressed Air System has been considered in this RA document.

## 5 Participants

| Name | Designation/ Department | Signature/ Date |
|---|---|---|
| | | |
| | | |
| | | |

## 6 Risk Management Process

A typical Risk management process consists of following steps:

- Risk Assessment:
  - Risk Identification
  - Risk Analysis
  - Risk Evaluation

- Risk Control
  - Risk Reduction
  - Risk Acceptance

- Result of Risk management processes
- Risk Review

- Risk Assessment consists of the identification of hazards and the analysis and evaluation of risks associated with exposure to those hazards.
  Risk identification is a systematic use of information to identify hazards referring to the risk question or problem description.
  Risk analysis is the estimation of the risk associated with the identified hazards. It is the qualitative or quantitative process of linking the likelihood of occurrence and severity of harm.

  Risk evaluation compares the identified and analyzed risk against given risk criteria. Risk evaluation considers the strength of evidence for all three of the fundamental questions.
  The output of a risk assessment is either a quantitative estimate of risk or a qualitative description of range of risk. In case of qualitative description the risk is expressed using descriptors such as “high”, “medium” or “low”.

- Risk control includes decision making to reduce and/ or accept risks. The purpose of risk control is to reduce the risk to an acceptable level. The amount of effort used of risk control should be proportional to the significance of the risk.
  Risk reduction focuses on processes for mitigation or avoidance of quality risk when it exceeds a specified (acceptable) level. Risk reduction might include actions taken to mitigate the severity and probability of harm.
  Risk acceptance is a decision to accept risk. Risk acceptance can be a formal decision to accept the residual risk or it can be a passive decision in which residual risks are not specified.
- The output/ result of the quality risk management process should be appropriately communicated and documented.

- Risk management should be an ongoing part of the quality management process. A mechanism to review or monitor events should be implemented.
- The output/ results of the risk management process should be reviewed to take into account new knowledge and experience.

This document applies the risk management principles to identify the risks associated with the design, Construction and operational features of the proposed sterile formulation facility.

The objectives of this risk assessment are to:

• Review the design around a structured methodology
• Identify the failure modes and associated risks
• Check if the proposed control measures are adequate
• Identify recommendations to obtain a more acceptable risk level if required

## 6.1 Identifying GMP risk

Identification of Risk associated with the equipment, is generally based on prior experience and the concerns of the participants of risk assessment document.

The risks identified are categorized as “GMP risk” or “Non-GMP risk”.

GMP is defined as “the practices which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.”

Thus, GMP covers all aspects of the manufacturing process: defined manufacturing process; validated critical manufacturing steps; suitable premises, storage, transport; qualified and trained production and quality control personnel; adequate laboratory facilities; approved written procedures and instructions; records to show all steps of defined procedures have been taken; full traceability of a product through batch records and distribution records; and systems for recall and investigation of complaints.

Thus those risks which might have a direct or indirect impact on the quality of the product are classified as “GMP risk”. Also, those risks which might result in regulatory guidelines non-compliance are also classified as “GMP risk”.
For example: The Hygiene level of the manufacturing areas has a direct impact on the quality of the Product. Thus, it is classified as GMP risk.
The “Non GMP” risks include risks related to EHS, operational and other non-critical hazards.

Following types of risks are mainly identified during risk assessment process:

- Risk related to hygiene level of the manufacturing and supporting areas
- Risks related to appropriate utilities and their control (eg. power source, compressed air etc.)
- Risks related to calibration/ preventive maintenance
- Risks related to protection of the environment and health & safety of personnel.
- Risks related to cleaning & sterilization
- Risks related to unidirectional flow of the material
- Risks related to cross contamination of the products
- Risks related to entry and exit of personnel and material.
- Risks related to all the environment features of the manufacturing areas.
- Risks related to requirement of particular rooms for different activities.

- Risks related to environment health and safety of personnel.

## 6.2 RISK ANALYSIS & EVALUATION

The risk analysis is performed using a qualitative basis of approach.

Qualitative analysis uses word form or descriptive scales to describe the magnitude of potential consequences/ impact and the likelihood that those consequences will occur.

The qualitative measures of likelihood includes descriptors like “Unlikely”, “Possible” and “Likely”, whereas the qualitative measures of consequence/ impact includes descriptors like “Minor”, “Moderate” and “Major”.

**Qualitative measures of likelihood**

| Level | Descriptor | Example detail description |
|---|---|---|
| 1 | Unlikely | May occur at some time |
| 2 | Possible | Might occur at some time |
| 3 | Likely | Will probably occur in most circumstances |

**Qualitative measures of consequence/ impact**

| Level | Descriptor | Example detail description |
|---|---|---|
| 1 | Minor | • No impact on the product quality or outcome of the equipment.<br>• Features required for easing equipment operation. |
| 2 | Moderate | • No direct impact on product quality/ outcome of equipment. However may indirectly affect the product quality.<br>• Minor effect on personnel health<br>• Used in the initial stage of operation, however it may affect the final output but those are not used for final release of output.<br>• Effect on environment such as clean room. |
| 3 | Major | • Features having direct impact on product quality/ outcome of equipment like contact parts MOC, Surface finish, Control system, Process air quality etc.<br>• Failure could lead to regulatory non-compliance.<br>• Loss/ damage to equipment or its critical sub-components<br>• Critical instruments not calibrated or not of desired range or accuracy.<br>• Proper supporting documentation not provided.<br>• Major effect on personnel health |

Based on the above parameters of likelihood and consequence a qualitative risk analysis matrix is prepared to identify the overall Level of Risk, as mentioned in table below.

**Qualitative risk analysis matrix – level of risk**

| Likelihood | Consequences/ Impact | | |
|---|---|---|---|
| | 1 – Minor | 2 – Moderate | 3 – Major |
| 1 (Unlikely) | Low | Medium | High |
| 2 (Possible) | Low | Medium | High |
| 3 (Likely) | Medium | High | High |

The final Risk level shall thus be described using descriptors such as “Low”, “Medium” & “High”, where each descriptor implies the following meaning:

**Low –** Risk can be accepted or ignored. These do not affect the final quality of the equipment/ system and it can be managed by routine procedures and are unlikely to need specific application of resources.

**Medium** – Risk required ongoing monitoring and review, to ensure level of risk does not increase. Otherwise managed by routine procedures.

**High** – Action plans must be developed, with clear assignments of individual responsibilities and timeframes.

## 7 Risk Assessment

In the following section a table is produced for the risk assessment. The significance or instruction for each column is described in the following paragraph.

Column 1 : **Serial number** of the Risk assessment item

Column 2 : **Process step/ Component**: Identify the process step or component associated with the risk.

Column 3 : **Risks:** Identify the type of risk associated with the process or component

Column 4 : Verify that whether risk have **GMP impact** in terms of Yes/ No.

Column 5 : **Justification:** Provide justification for declaring both Yes/ No for GMP impact in column 4.

Column 6 : For the risk **other than of GMP impact**, write that what is/ are the type of risks e.g. EHS, operational, etc.

Column 7 : **Justification:** Provide justification for considering the risk.

Column 8 : **Risk level:** Determine the risk level as High, Medium or low based on the impact.

Column 9 : **Risk Control:** It is further divided into the following three sections:

Column 9a : **Mitigation Method:** Write the risk mitigation strategy as considered in the design.

Column 9b : **Residual risk level:** After the risk mitigation what is the residual risk level, whether it is Acceptable, Low or Medium.

Column 9c : **Test document:** Write the test point where the risk mitigation strategy will be verified.

Column 10 : **Status of RA:** Mention the status of the Risk assessment point i.e. whether it is ‘Closed” or “Open”, after the execution/ approval of the Test document.

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| S.No. (1) | Process steps/ component (2) | Risk (3) | GMP Risk Yes/ No (4) | Justification (5) | Other Risk type (6) | Justification (7) | Risk Level (8) | Risk Control (9) | | | Status of RA (10) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Mitigation Method (9a) | Residual risk level (9b) | Test Document (9c) | |
| **Supply Air** | | | | | | | | | | | |
| 1. | Supply air | Quality of the supply air is not good, contaminated with vapours. | Yes | Vapours will pass through the compressor and contaminate the products. | No | NA | High | The suction port of the Compressor will be installed in inverted position to avoid direct entry of vapours. | Acceptable | IQ & OQ | |
| 2. | Supply air | Insects and heavy dust particles in the air. | No | As pre filters and fine filters are there, it will arrest the same. | Operational | Choking of the pre-filter leads to easy damage of filters. | Medium | Wire mesh will be fixed on the suction port followed by coarse filters to control these particles. | Acceptable | IQ & OQ | |
| 3. | Supply air | Source supply air is having high humidity. | Yes | Final air quality cannot be maintained | No | NA | High | • The compressed air system should have inbuilt moisture Separator or other mechanism to handle the high humidity.<br>• Air compressor should have an air dryer at the discharge line for removing moisture. | Acceptable | IQ & OQ | |
| 4. | Compressor | The compressor is not meeting the required pressure | Yes | Insufficient performance of connected systems | No | NA | High | • Air compressor shall be single/double stage oil free type or other suitable design to provide the required output.<br>• Motor shall be design to meet the plant capacity.<br>• Air compressor shall have provision to measure the pressure. | Acceptable | IQ & OQ | |

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| | | | | | | | | Mitigation Method (9a) | Residual risk level (9b) | Test Document (9c) | |
| 5. | Compressor | Compressed air supply gets stopped during maintenance. | Yes | Routine production activity may get disturbed. | Operational | Routine maintenance schedule may get delayed due to continuous production operation. | High | Stand by compressor will be considered for trouble free continuous operation. | Acceptable | IQ & OQ | |
| **Coolant** | | | | | | | | | | | |
| 6. | Coolant | Inadequate coolant | Yes | Temperature of the air will be high hence also affect the moisture content | No | NA | High | • Cooling water shall be used as coolant in both inter cooler and after cooler.<br>• Limit and pressure switches to ensure the availability of water flow.<br>• Cooling water inlet and outlet temperature should be monitored and regulated. | Acceptable | IQ & OQ | |
| **Intercooler** | | | | | | | | | | | |
| 7. | Inter cooler | Air output temperature is high | No | NA | Operational | The downstream system should be compatible with that temperature | Medium | The inter cooler to be properly designed to take the load. | Acceptable | IQ & OQ | |
| 8. | Inter cooler | Material of construction of the exchanger is not compatible. | No | NA | Operational | As the moisture is high, it can leads to corrosion of the exchanger. | Medium | Copper tube for air passing is recommended to avoid the same. | Acceptable | IQ | |
| 9. | Inter cooler | Cooling media is not available | No | NA | Operational | Improper heat transfer leads to improper function of the downstream system. | Medium | • Cooling water / Air can be used as a cooling media.<br>• Alarm system to be initiated with shut down the system if cooling water is not | Acceptable | IQ & OQ | |

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| | | | | | | | | available. | | | |
| 10. | Inter cooler | Scale formation in the shell side of the exchanger. | No | NA | Operational | Scale formation leads to improper heat transfer. | Medium | Soft water to be used for the same to avoid the scale formation. | Acceptable | IQ | |
| 11. | Inter cooler | The air coming out of the intercooler has water droplets due to the cooling effect. | Yes | The moisture will be carried with the air. | Operational | The heavy moisture will increase the load on the Air drier. | Medium | Moisture separator will be considered after the inter cooler with auto drain valve to drain the moisture. | Acceptable | IQ & OQ | |
| 12. | Inter cooler | Possibility of pressure built up in the intercooler. | No | NA | Operational/ EHS | Possibility is high due continuous supply of pressurized air. | High | • Safety relief valve will be provided on the inter cooler with set limit to handle the same.<br>• Pressure gauge will be provided to monitor of the intercooler. | Acceptable | IQ & OQ | |
| **After Cooler** | | | | | | | | | | | |
| 13. | After cooler | Air output temperature is high | No | NA | Operational | The downstream system should be compatible with that temperature | Medium | • The After cooler to be properly designed to take the load.<br>• Shell and tube type exchanger is advisable with copper tube for better heat transfer.<br>• Minimum pressure check valve shall be installed before after cooler | Acceptable | IQ & OQ | |

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| | | | | | | | | Mitigation Method (9a) | Residual risk level (9b) | Test Document (9c) | |
| 14. | After cooler | Material of construction of the heat exchanger is not compatible. | No | NA | Operational/ Financial | As the moisture is high, it can leads to corrosion of the heat exchanger. | Medium | Copper/aluminium tube for air passing is recommended to avoid the same. | Acceptable | IQ | |
| 15. | After cooler | The air coming out of the After cooler has water droplets due to the cooling effect. | Yes | The moisture will be carrier with the air. | Operational | The heavy moisture will increase the load on the Air drier. | Medium | Moisture separator will be considered after the cooler with auto drain valve to drain the moisture. | Acceptable | IQ & OQ | |
| **Air Dryer** | | | | | | | | | | | |
| 16. | Air dryer | Air humidity | Yes | Too high air humidity may lead to corrosion.<br>Too high air humidity may lead to microbial growth and agglomerations of product | No | NA | High | • Dew point (≤-40°C) & water content, class 2 according ISO 8573-1.<br>• Desiccant type or heatless air dryer should be recommended for the same. | Acceptable | IQ & OQ | |
| 17. | Air dryer | The production will be disturbed during the regeneration. | Yes | The down steam system will be disturbed | No | NA | High | The system shall be auto regenerated and for the operation two tower systems shall be considered when one under functioning the other will be get regenerated. | Acceptable | IQ & OQ | |
| **Air Quality** | | | | | | | | | | | |
| 18. | Air Quality | Insufficient air Quality | Yes | Air quality must be suitable for the intended operation all the time | No | NA | Yes | • Air quality according to current EP, and USP and in-house requirement (particle size, - residuary oil , dew point & water | Acceptable | IQ, OQ & PQ | |

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| | | | | | | | | Mitigation Method (9a) | Residual risk level (9b) | Test Document (9c) | |
| | | | | | | | | content, viable and nonviable count, Hydrocarbon content)<br>• SOP: For Operation, Cleaning and preventive maintenance of system, filter, definition of life of filter units | | | |
| 19. | Air Quality | Pressure drop / variation / pressure stroke / pressure repulsion | Yes | Air quality must be suitable for the intended operation all the time | Operational / EHS | Cannot operate the system connected with it. | High | Air Receiver to be provided after Air dryer. | Acceptable | IQ | |
| **Air Receiver** | | | | | | | | | | | |
| 20. | Air Receiver | The capacity of the receiver is not sufficient | No | It will not affect the quality of the air. | Operational | Insufficient to satisfy operational needs | High | Suitable capacity tank to be designed. | Acceptable | IQ | |
| 21. | Air Receiver | The receiver will be over pressured | No | It will not affect the quality of the air. | Operational / EHS | Continuous running of compressor leads to pressure built up in the tank. | High | • The tank shall be designed with safety valve.<br>• The tank shall be designed with consideration of all safety aspects.<br>• Pressure gauge shall be provided on the receiver tank | Acceptable | IQ & OQ | |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Mitigation Method (9a) | Residual risk level (9b) | Test Document (9c) | |
| 22. | Air Receiver | Possibility of water collection in the Air Receiver | Yes | Will not meet the final quantity of air. | No | NA | Medium | Auto drain valve or manual drain valve shall be considered on the receiver tank.<br>The blow down interval can be adjusted based on requirement. | Acceptable | IQ & OQ | |
| **Air Filter** | | | | | | | | | | | |
| 23. | Air Filter | Particles from the receiver block the pipelines. | No | As final filter is there in the user point, it will not affect the quality of the air. | Operational | Pipelines will be blocked and leads to productivity loss. | Medium | 5.0, micron 1.0 Micron followed by 0.1 Micron filter should be considered at the outlet of Air receiver so as to arrest the particles. | Acceptable | IQ | |
| **Distribution System** | | | | | | | | | | | |
| 24. | Distribution piping. | High pressure than the desired limit | No | NA | EHS | High pressure may cause damage in piping system | Medium | Pressure switch, safety valves are considered in the distribution system addressing the same. | Acceptable | IQ | |
| 25. | Distribution piping. | Pressure leakage may occur | Yes | May leads to pressure drop in supply line as well as low pressure will observed at user points | No | NA | High | Pressure leak test report of pipeline should be available. | Acceptable | IQ | |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Mitigation Method (9a) | Residual risk level (9b) | Test Document (9c) | |
| 26. | MOC of pipe | MOC of the pipe is not compatible. | Yes | Corrosion and leads to particle shedding. | No | NA | Medium | PPR/ Aluminium /SS 316 or better pipes shall be considered to avoid the same based on the criticality for distribution of air manufacturing area (Product contact surfaces). | Acceptable | IQ | |
| 27. | Distribution piping | Filters are not functioning properly. | Yes | Filter is intended as additional guard (particle from piping system) | No | NA | High | • Filter shall ensure specified air quality.<br>• Gaskets, seals and O-rings should be constructed of Food grade / non-toxic polymeric materials only.<br>• SOP: preventive maintenance, definition of filter change intervals | Acceptable | IQ & SOP | |
| 28. | Piping | Moisture / condensate in dead ends / dead legs | Yes | Forming of condensate is almost excluded due to dryness of air.<br>Piping shall be executed as loop (per level) | No | NA | Medium | Draining shall be possible at lowest point of loop | Acceptable | IQ | |
| 29. | Piping | No sampling points are considered in the distribution points for testing. | Yes | It is GMP requirement to ensure the quality before using. | N0 | NA | High | Sampling points will be considered in the piping routing layout and to be designed as per that. | Acceptable | IQ & OQ | |
| 30. | Points of use | Possibility of particle flow from the pipe line to the user end/ System. | Yes | Contamination of products. | Operational | Particles may choke the inlet of critical system. | Medium | 0.2 Micron filters will be placed on all critical user points to arrest the same. | Acceptable | IQ & OQ | |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Mitigation Method (9a) | Residual risk level (9b) | Test Document (9c) | |
| 31. | Points of use | High pressure than the desired requirement for the system High pressure at user points. | No | NA | Operational | High pressure may damage the system. | High | Those critical system has inbuilt pressure regulation system to address the issue. | Acceptable | IQ | |
| 32. | Points of use | Too many consumer units, pressure drop | Yes | Insufficient machine operation (control air) | No | NA | High | • The distribution System is connected to the plant system which comprises more than one compressors (redundancy)<br>• Pressure checking at all user points during qualification. | Acceptable | IQ & OQ | |
| 33. | Points of use | All the user points are not considered in the distribution piping. | Yes | Compressed air will not be available. | No | NA | High | Installation of piping with respect to the pipe routing of compressed air based on the user points considered. | Acceptable | IQ | |
| 34. | Welding | Welding not proper | Yes | Corrosion may be possible particle émission | No | NA | High | • Welder reference certificates shall be available for orbital welding.<br>• Care shall be taken to maintain full alloying even in the outermost layers of the surface to reduce oxidation or heat tint.<br>• Least number of joints shall be considered during designing. | Acceptable | IQ | |
| **Operation** | | | | | | | | | | | |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Mitigation Method (9a) | Residual risk level (9b) | Test Document (9c) | |
| 35. | Process compressed air | Quality relevant parameters are not controlled | Yes | Process compressed air must fulfil quality requirements | No | NA | High | System qualification | Acceptable | IQ & OQ | |
| 36. | Process compressed air | System performance not sufficient | Yes | Influence on product quality possible, if sufficient amount of process air is not available | No | NA | High | System design to be adapted to fulfil the need | Acceptable | IQ & OQ | |
| **Maintenance** | | | | | | | | | | | |
| 37. | Maintenance | Malfunctions due to worn parts | Yes | Basic GMP requirement | No | NA | High | • Machine shall be easy to maintain.<br>• Preventive maintenance procedure should be available<br>• The unit must contain necessary protection devices to ensure that the equipment & the article remain in a safe condition. | Acceptable | IQ & SOP | |
| **Safety** | | | | | | | | | | | |
| 38. | Safety | No safety against high pressure, Hot surfaces, Rotating parts, Noise level etc. | No | NA | Operational/ / EHS | High pressure may leads to an accident | High | • Safety valve shall be provided.<br>• Warning stickers on all hot surfaces.<br>• Appropriate closure of all the rotating parts. | Acceptable | IQ & OQ | |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Mitigation Method (9a) | Residual risk level (9b) | Test Document (9c) | |
| | | | | | | | | • Noise level of the system shall be less than 80 db of 1m distance from the system. | | | |
| 39. | Safety | Proper pipe identification system not available. | No | NA | Operational | Improper identification leads to the mistake of operating of other utility instead of air. | High | Proper colour coding to be practised to avoid such mistakes. | Acceptable | IQ & SOP | |
| 40. | Emergency stop | Instantaneous stopping of the machine not possible | No | Does not have any impact on quality of the product | EHS | Emergency stop function is required for equipment, personnel and product protection | High | Emergency stop with alarm to be installed on control panel. | Acceptable | IQ | |
| 41. | Noise level | More noise is produced by the compressor during the operation. | No | Does not have any impact on quality of the product | EHS | High noise may cause deafness and anxiety | Medium | • Compressor should be provided with anti-vibration mountings to reduce vibration and noise.<br>• Noise level shall be below 80 db at a distance of 1 m from the equipment.<br>• Operator should bear ear plug. | Acceptable | IQ & OQ | |
| **Measuring Instrument** | | | | | | | | | | | |
| 42. | Measuring Instruments | Measuring Instruments not suitable | Yes | Improper measurements | No | NA | High | • Measuring Instruments must have a suitable measuring range.<br>• Operational range of | Acceptable | IQ & OQ | |

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| | | | | | | | | Mitigation Method (9a) | Residual risk level (9b) | Test Document (9c) | |
| | | | | | | | | Measuring Instruments > equipment working range.<br>• Measuring Instruments must have appropriate accuracy. | | | |
| 43. | Measuring instruments | Measuring instruments not calibrated | Yes | Non calibrated measuring instruments may lead to false information | No | NA | High | • Measuring instruments should be calibrated (full loop calibration). | Acceptable | IQ & OQ | |
| 44. | GMP relevant measuring instruments | Instruments cannot be dismounted | Yes | Defective instruments must be dismounted for exchange and calibration | No | NA | High | • Mounting of instruments must give the possibility for dismounting and replacement<br>• Constructional solution: easy access for re-calibration activities shall be given. | Acceptable | IQ | |
| **Cleaning** | | | | | | | | | | | |
| 45. | Cleaning | Improper cleaning | Yes | Accumulation of particles leading to alteration in system performance as well as alteration in product quality | No | NA | High | Proper cleaning method has to be provisioned.<br>All gaskets provided to avoid leakage should be amenable for easy removal & re- fixing for cleaning. | Acceptable | IQ & OQ | |
| 46. | Cleaning | Difficulty in cleaning | Yes | Parts need to be dissembled for proper cleaning | No | NA | Medium | The design shall ensure adequate clean ability | Acceptable | IQ & OQ | |
| 47. | Draining | Improper Drain ability or no Drain ability | Yes | Residual water may cause microbial growth & may increase humidity in | No | NA | High | • Drains shall be located at appropriate locations & proper slope shall be provided in the drain tray. | Acceptable | IQ | |

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## RISK ASSESSMENT FOR COMPRESSED AIR SYSTEM

| S.No. (1) | Process steps/ component (2) | Risk (3) | GMP Risk Yes/ No (4) | Justification (5) | Other Risk type (6) | Justification (7) | Risk Level (8) | Risk Control (9) | | | Status of RA (10) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Mitigation Method (9a) | Residual risk level (9b) | Test Document (9c) | |
| | | | | the rooms | | | | • The pipe surface shall be buffed to the extend for easy cleaning operations internally and externally. | | | |
| **Control System** | | | | | | | | | | | |
| 48. | Man-machine Interface | Process / process status not visible for operating personnel | Yes | Operating personnel must have knowledge of the process status | No | NA | High | Machine shall be fitted with adequate display and clean room suitable key board for operation. | Acceptable | IQ | |
| 49. | Man-machine Interface | Display language not identified. | Yes | Pre-requisite for the GMP compliant operation | No | NA | High | The language on the display of MMI should be English language only. | Acceptable | OQ | |
| 50. | PLC / Control system | Malfunction | Yes | Correct function basic requirement for GMP-compliant operation | No | NA | High | • Supplier analysis (quality management system for software and control system hardware development)<br>• Input-output verification shall be performed.<br>• The system must contain all necessary protection devices to ensure that the equipment and article remain in safe condition. | Acceptable | OQ | |
| 51. | PLC/ Control System | Controlling of critical process parameters not possible | Yes | Basic GMP requirement | No | NA | High | PLC should be able to control critical process parameters | Acceptable | OQ | |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Mitigation Method (9a) | Residual risk level (9b) | Test Document (9c) | |
| 52. | PLC/ Control System | Control system does not able to detect failures and generate alarms | Yes | Operating personnel will not be able to know the error occurred in the systems. | No | NA | High | • Failure of set parameters gets indicated as alarms and machine stops.<br>• Alarm list has to be defined. | Acceptable | OQ | |
| 53. | PLC / Control system | Parameters and their status not displayed | Yes | Operating personnel will not be able to know the required parameters and value hence may cause alteration in product quality as well as damage to machine. | No | NA | High | • Parameters and their status should remain displayed at each process stage.<br>• The flow of the process shall be provided with the help of arrows. | Acceptable | OQ | |
| 54. | PLC/Control Parameters settings | Parameter settings not identified universally | Yes | Basic GMP requirement | No | NA | High | Parameters settings should be in numeric only. | Acceptable | OQ | |
| 55. | PLC/ Control System | Time measurement incorrect | Yes | Incorrect Process time leads to uncleared information | No | NA | High | • PLC clock verification<br>• SOP “calibration and maintenance”<br>• Time synchronization of system | Acceptable | OQ/ SOP | |
| 56. | Accessibility to PLC | No protection of PLC against manipulation & changes. | Yes | Basic GMP requirement. | No | NA | High | • Minimum 3 level password protections should be provided.<br>➢ Level 1: for operator settable parameters.<br>➢ Level 2: for editing cycle parameters.<br>➢ Level 3: for admin/ engineering level setting. | Acceptable | OQ | |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Mitigation Method (9a) | Residual risk level (9b) | Test Document (9c) | |
| 57. | Power | System will restart on its own during Power regain after failure. | No | NA | EHS | May end in accident due to unnoticed starting of the system. | High | • During power failure system will come safe to the shutdown mode.<br>• Restart of the system will be only through Human intervention. | Acceptable | IQ & OQ | |
| 58. | Power | Alteration in system performance | Yes | Disturbance of the conditions may lead to alteration in product quality | No | NA | High | On resume of power system will start normally. | Acceptable | OQ | |
| **Documentation** | | | | | | | | | | | |
| 59. | User | Faulty operation & maintenance | Yes | SOPs are basic GMP-requirement | No | NA | High | • All end-users have to be trained on SOPs<br>• Training of SOPs has to be documented<br>• Training on the job of end users by vendor<br>• Training on operation, setting parameters, trouble shooting & maintenance related activities. | Acceptable | OQ & SOP | |
| 60. | User | Operation SOP does not contain proper information and user may operate system | Yes | User may make a wrong decision. | No | NA | High | • System operation SOP must be reviewed with all aspects and approved.<br>• Vendor shall provide execution support to the user to complete all stages of the qualification report. | Acceptable | OQ | |
| 61. | User | Unauthorized person tries to start/stop the system | Yes | Untrained persons may damage the system or product quality may be affected | No | NA | High | • System should not start without password.<br>• Key-switch should be provided for system power up. | Acceptable | IQ & OQ | |

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## RISK ASSESSMENT FOR COMPRESSED AIR SYSTEM

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|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Mitigation Method (9a) | Residual risk level (9b) | Test Document (9c) | |
| 62. | Vendor documents | Technical documentation from vendor not adequate | Yes | Adequate technical documentation is basic GMP requirement | No | NA | High | Vendor documentation (English) shall comprise at least:<br>➢ DQ, IQ and OQ<br>➢ Material certificates<br>➢ O & M manual<br>➢ Calibration certificates<br>➢ Software backup<br>➢ Change Parts list (sufficient detailed – part no., supplier, type)<br>➢ Drawings:<br>- P&I-diagrams<br>- Electrical diagrams<br>➢ -As built GA drawing<br>➢ Filter certificates<br>➢ Hydrotest Report<br>➢ Running trial certificate.<br>Certificate of bought out components. | Acceptable | IQ | |

## 8 Summary & Conclusion

- The Risk Assessment was performed to establish the design parameters of the equipment so as to meet the desired performance of the equipment i.e. Compressed Air System.
- The critical risks pertained to GMP and other than GMP, were analyzed with justification and mitigation procedures.
- For each recognized GMP-risk and other than GMP risks, necessary measures are defined. Organizational measures, like SOPs, are also possible measures for special GMP-risks. The availability of these SOPs will be checked during the performance of the OQ.
- The risks where conceptual procedures shall be employed, standard operating procedures (SOPs), Preventive maintenance schedules, Certificates and related documents indicated as mitigation procedures shall be ensured at respective test points

*"It is concluded that the **Risk Assessment** performed for the equipment will prevent the risk of failures of critical parameters during, design commissioning, installation, operation and performance of the equipment".*

## 9 Abbreviations

| | | |
|---|---|---|
| EU-GMP | : | European – Good Manufacturing Practice |
| EHS | : | Environment Health Safety |
| PLC | : | Programmable Logic Controller |
| MMI | : | Man Machine Interface |
| GMP | : | Good Manufacturing Practice |
| RA | : | Risk Assessment |
| NMT | : | Not More Than |
| SOP | : | Standard Operating Procedure |
| USFDA | : | United State Food & Drug Association |
| ISO | : | International Organization for Standardization |
| SS | : | Stainless Steel |
| db | : | Decibel |
| DQ | : | Design Qualification |
| IQ | : | Installation Qualification |
| OQ | : | Operational Qualification |
| PQ | : | Performance Qualification |
| O&M | : | Operation and Maintenance |
| GA | : | General Arrangement |
| IPSI | : | Integrated Project Services International, New Delhi |

## 10 Revision History

| Date | Revision | Reason for Revision |
|---|---|---|
| | 00 | New Document |