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Risk Assessment Document HVAC System
System ID:

Revision index

Revision	Date	Reason for revision
00		First Issue

FAILURE MODE EFFECT ANALYSIS FOR HEATING VENTILATION AND AIR CONDITIONING SYSTEM

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FAILURE MODE EFFECT ANALYSIS FOR HEATING VENTILATION AND AIR CONDITIONING SYSTEM

1.0 Approval 1 m

This document is prepared0 by the validation team of ……..for the project OSD Formulations Facility' of ……. under the authority of their Project Manager. Hence, this document before being effective shall be approved by the QA team of ……., and authorized by the appropriate Project Authority.

PREPARED BY		
NAME	**DE IGNATION**	**SIGNATURE /DATE**

CHECKED BY		
NAME	**DE IGNATION**	**SIGNATURE /DATE**
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APPROVED BY		
NAME	**DESIGNATION**	**SIGNATURE/ DATE**

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FAILURE MODE EFFECT ANALYSIS FOR HEATING VENTILATION AND AIR CONDITIONING SYSTEM

2.0 Introduction

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According to the definition, given in Annex 15, 20 to the EU-GMP-Guide and ICH Q9 Quality risk management, 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 is performed as basic GMP/EHS-Risk assessment, which shall help to identify important GMP/EHS-requirements.

3.0 Aim of the 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.

4.0 Reference Documents

S.No.	Document Title	Document Number
1.	Validation master plan	
2.	Project validation plan	

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5.0 System Description

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This risk assessment is conducted for the HVAC System of the Sex hormone OSD Formulations Facility and consists of the air handling unit and treated fresh air unit

The HVAC system for this Sex hormone OSD Formulations Facility has been designed for obtaining and maintaining the required working conditions by means of providing:

- Adequate ventilation.
- Control over air pressure, microorganisms, dust, humidity and temperature
- Air filtration systems
- Desired level of cleanliness class.
- To ensure containment of product.

Most of the possible risk concerning the handling/ operation of the HVAC has been considered in this RA.

6.0 Participants

Name (block letters)	Function	Signature

7.0 Risk Management Process

A typical Risk management process consists of following steps:

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

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- Risk Control
  - Risk Reduction 0
  - 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 any equipment, which is going to be procured and installed in the facility.

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7.1 Identifying GMP risk

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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 MOC of the product contact part 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 product contact materials for equipment and containers (eg. Selection of SS grade, gaskets, lubricants etc.)
- Risks related to appropriate utilities and their control (eg. Steam, gases, power source, compressed air etc.)
- Risks related to calibration/ preventive maintenance
- Risks related to protection the environment and health & safety of personnel.
- Risks related to cleaning & sterilization
- Risks related to control system of the equipment
- Risks related to product loss

7.2 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”.

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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. • Features required for easing equipment operation.
2	Moderate	• No direct impact on product quality/ outcome of equipment. however may indirectly affect the product quality. • Minor effect on personnel health • Used in the initial stage of operation, however it may affect the final output but those are not used for final release of output. • 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. • Failure could lead to regulatory non-compliance. • Loss/ damage to equipment or its critical sub-components • Critical instruments not calibrated or not of desired range or accuracy. • Proper supporting documentation not provided. • 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

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

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8.0 Risk Assessment 1 m

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 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 there is **GMP risk.**

Column 5: **Justification**: Provide justification for declaring both yes/no for GMP Impact in column 3.

Column 6: For the risk **other than of GMP risk,** write what is the other type of risks e.g. EHS, Operational.

Column 7: **Justification**: Provide justification for considering any 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 following three sections

Column 9a: **Mitigation Method**: Write the risk mitigation strategy as considered in 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: **Verification**: Write the test point where the risk mitigation strategy will be verified.

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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S. No	Process Steps/Component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
1.	Supply air fans	• Required amount of air is not sucked • Improper functioning of the blower (low/high flow/static pressure) • MOC of the blower is not compatible.	Yes	If the blower doesn't meet the required specifications then the required CFM and specified room conditions cannot be achieved.	No	NA	High	• Fan of desired CFM is selected and installed in the AHU. • BMS shall be provided for the ON/OFF status of the supply air fan • Room conditions within process rooms is to monitored • An alarm is to be initiated in case of deviations from the specified limits • The MOC of the blower shall be selected accordingly. MS with coating of Epoxy is recommended • SOP: preventive maintenance is to be developed	Acceptable	**V** IQ & OQ

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S.No.	Process Steps/Component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
Cooling and heating coils										
2.	Cooling coils	Insufficient performance, breakdown	Yes	Room Temperature/ RH may deviate from specifications.	Operational	Loss of energy	Medium	• Pipelines and coils are pressure tested • BMS system shall measure and display chilled and hot water temperature • Supply pressure and temperature monitoring and out of limit room temperature/RH is to be alarmed	Acceptable	IQ & OQ
3.	Air	Suction of polluted air from condensate drain	No	Downstream filter will take care	Operational	The filter shall be choked frequently leading to extra maintenance.	Low	• Condensate drain should be provided with suitable arrangement • Air break/siphon is provided in drain line	Acceptable	IQ
3-way valves in cooling/ heating coil										

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S. No	Process Steps/Component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
4.	3 way Valves	Improper function	Yes	May deviate from Temperature/ RH specifications	No	NA	Medium	• Proper valve function is to be verified during qualification • SOP: Preventative Maintenance is to be prepared • Function monitoring in BMS system is to be done. Supply pressure and temperature monitoring and out of limit room temp/RH is to be alarmed	Acceptable	IQ & OQ
Drain Connections										
5.	Drain	Improper draining of the condensate and excess supplies	Yes	Stagnant water may lead to bacterial growth in AHU.	No	NA	Low	Proper slope / pitch shall be provided.	Acceptable	IQ
Differential pressure port across HEPA filter										

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S.No.	Process Steps/Component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
6.	Differential pressure across HEPA	No Differential pressure sensor available	Yes	Filter status cannot be monitored	No	NA	Medium	Differential pressure transmitter shall be provided	Acceptable	IQ
Piping										
7.	Piping	Leakage	No	No direct relation with the supply air	Operational	Loss of energy	Low	Pressure test of the pipes is to be done	Acceptable	IQ
Ducts										
8.	Duct	Duct eroded / Leakage	Yes	• Contamination or leakage of air can take place • Leakage may lead to disturbances in temp./ RH conditions and room pressures	Operational	Leakages will lead to loss of energy.	High	• Duct's MOC is of Galvanized iron • Installation leak test is to be carried out and correction if any leak found. • USFDA approved material gasket to be used in all joints.	Acceptable	IQ& OQ

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S. No	Process Steps/Component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
9.	Duct	Improper insulation	Yes	Air temperature cannot be maintained	Operational	Energy losses	Medium	• Proper insulation is provided • Insulation is to be verified during installation of ductwork • Insulation material shall be Nitrile rubber with aluminum cladding	Acceptable	IQ
10.	Duct	Transmission of sound & vibrations	No	It will not affect the final air quality.	EHS	Direct contact of duct work with building and other utility systems / installations and heavy sound due to vibration.	Medium	- System shall have anti-vibration mounting - Duct shall be isolated from fans through canvas connections	Acceptable	IQ & OQ
Dampers										

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S. No	Process Steps/Component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
11.	Manual Damper	Non- Availability, Improper size and malfunctioning	Yes	Specified room conditions (air exchange rates, pressure cascade, temperatures, humidity) may not be maintained	EHS	Uncomfortable conditions for personnel	Medium	• Availability, Sizes is to be checked with the drawings. • Damper operation is to be verified during OQ • Room conditions within process rooms is to be monitored	Acceptable	IQ&OQ
Motorized damper										

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QUALITY ASSURANCE DEPARTMENT

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S. No	Process Steps/Component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
12.	Motorized Damper	Non- Availability, Improper size and malfunctioning	Yes	Specified room conditions (air exchange rates, pressure cascade, temperatures, humidity) may not be maintained	EHS	Uncomfortable conditions for personnel	Medium	• Availability, Sizes is to be checked with the drawings. • Motorized dampers shall be provided in rooms to regulate room pressure • Air mixing damper shall be motorized to regulate air flow • Motorized damper operation is to be verified during OQ and routine preventive maintenance • Shall be provided in rooms for regulating pressure	Acceptable	**V** IQ & OQ
Nuts & bolts in clean room										
13.	Nuts and Bolts	Not as per clean room design	Yes	All items shall be suitable for clean room, must not shed /deposit particles/dust.	Operational	Difficult for the operator for cleaning	Low	Counter sunk / clip/ push type fixing arrangement shall be considered in design.	Acceptable	IQ

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S. No	Process Steps/Component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
Insect mesh and interlocking of door										
14.	Insect mesh	Not provided	No	Downstream coarse filter takes care	No	NA	Low	HDPE insect mesh is provided to control insects coming through exhaust ducts.	Acceptable	IQ
15.	Interlocking	The casing door may open during the blower running.	No	It will not affect the final air quality.	Operational/ Financial	Downstream filter will be chocked due to unfiltered air.	High	Interlock will be made with the motor and the door to stop the motor when the door opens.	Acceptable	IQ & OQ
Pre-filter										
16.	Coarse filter (E - 4)	Filter doesn't fit tight in frame, filter damaged	No	Filter for pre-conditioning of air Downstream fine filters F6 will takes care if G4 fails	Operational	Overload on the downstream filter shall lead to frequent maintenance	Low	• Routine check and preventive maintenance is to be done.	Acceptable	IQ

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S. No	Process Steps/Component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
17.	Bag Filter (Fine filter)	Filter doesn't fit tight in frame, filter damaged	No	Filter serves for pre-conditioning of air Downstream fine filters takes care	Operational	Overload on the downstream filter shall lead to frequent maintenance	Low	• Monitoring of differential pressure across filter is to be done. • BMS shall provide clean/dirty display • SOP: preventive maintenance is to be developed.	Acceptable	IQ

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S. No	Process Steps/Component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
18.	Filters	Filter chocking.	Yes	Desired quantity of air will not be supplied or differential pressure and air changes could not be achieved	No	Operational: Over load on the Blower and high energy consumption.	High	• The pre filters shall be non-metallic, non-particle shedding, and Synthetic washable (HDPE) type. • Differential pressure across the filter shall be measured by differential pressure switch • Alarm shall be produced in the BMS in case of differential pressure gone out of the limit • SOP to be made for proper interval of cleaning of filters.	Acceptable	IQ & OQ
19.	Filters	Sufficient space not available for filter removing and cleaning activity.	Yes	Required quantity and quality cannot be supplied.	Operational / EHS	Difficult in removing the filter and cleaning.	High	Sufficient space between the filters will be provided for easy cleaning and filter integrity testing.	Acceptable	IQ & OQ

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S. No	Process Steps/Component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
20.	Filters	Filter doesn't fit tight in frame, filter damaged	No	Filter serves for pre-conditioning of air Downstream HEPA takes care	Operational	Overload on the downstream filter shall lead to frequent maintenance	High	• BMS is provided to provide clean/dirty display • Cleaning of filter shall be done as per SOP • SOP: preventive maintenance is to be developed.	Acceptable	IQ & OQ
Variable Frequency Drive (VFD) for supply fan										

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S. No	Process Steps/Component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
21.	VFD	Improper function / defect	Yes	Air change rates and pressure cascade may not be maintained	No	NA	Medium	• Performance of VFD is to be monitored in BMS by verifying the downstream flow by providing Air flow sensor output • Check for correct functioning during qualification and routine maintenance is to be done • SOP: preventive maintenance is to be developed.	Acceptable	IQ & OQ
HEPA in Plenum										
22.	HEPA filter (EU-13)	Integrity test failure	Yes	Hygiene level in the room will not be maintained	No	NA	High	• POA port is provided to check Filter integrity after installation and at regular interval	Acceptable	IQ & OQ

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S. No	Process Steps/Component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
23.	HEPA filter (EU-13)	Differential pressure across the HEPA filter cannot be monitored	Yes	Filter chocking	No	NA	High	• Differential pressure transmitter shall be provisioned in the design to monitor the pressure drop across the HEPA filter • Differential pressure shall be visible in the BMS	Acceptable	IQ & OQ
24.	HEPA filter (EU-13)	Filter doesn't fit tight in frame	Yes	filter will damage	No	NA	High	• Suitable space shall be provided to fit HEPA filter • SOP: preventive maintenance is to be developed	Acceptable	IQ
25.	HEPA (EU13) Bag in bag Out	The exhaust air is not filtered	No	Does not affect the quality of the product	EHS	Exhaust air may contaminate the environment	Low	• Safe change Bag in bag out HEPA filter should be provided in the exhaust duct.	Acceptable	IQ
Product processing area										

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S. No	Process Steps/Component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
26.	Temperature	Temperature is out of limit	Yes	Environmental conditions will not be suitable for operation	Operational	Not suitable for human working	High	• AHU design is made to achieve desired temperature. • Temperature sensor shall senses the room temperature and accordingly regulate the operation of chilled water control valve or heaters to maintain required temperatures within range. • Out of limit condition is alarmed • SOP: Regular monitoring of room temperature is to be done.	Acceptable	IQ & OQ

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S. No	Process Steps/Component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
27.	Reletive Humidity	RH is out of limit	Yes	Environmental conditions will not be suitable for operation	No	Operational/ Not suitable for human working	High	• Room RH shall be be monitored and controlled through the individual room heaters • Out of limit condition is alarmed • SOP: Regular monitoring of room temperature, Pressure and RH is to be done.	Acceptable	IQ & OQ

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S. No	Process Steps/Component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
28.	Hygiene zone	Room condition parameter does not meet specified hygiene class	Yes	Environmental conditions will not be suitable for operation	No	NA	High	• AHU system design is based on the requirement of hygiene zone. • Qualification of the room hygiene class is to be done. • Sequence of AHU operation to be established and study during qualification. • Return air shall be picked up through return air risers with low level pick-up to provide vertical airflow pattern in class ISO 8 At rest & ISO 8 in Operation. • Area cleaning and monitoring is to be done. • Maintenance and monitoring of pressure cascade is to be done.	Acceptable	IQ, OQ & PQ.

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S. No	Process Steps/Component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
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29.	Differential pressure	Differential pressure between two different hygiene zone is not maintained	Yes	Air may enter in higher hygiene zone from lower hygiene area	None	NA	Medium	• A higher pressure cascade is designed from higher to lower hygiene zone. • Regular monitoring of the differential pressure is to done. • Measurement, display and control of room differential pressure by BMS	Acceptable	IQ & OQ
30.	Air filtration	Air contaminated with product can cross contaminate other rooms, handling different product as recirculation of air is performing throughout the system.	Yes	Cross contamination	No	NA.	High	• All process rooms are provided with diffuser. • Manual dampers are provided to exhaust the contaminated air if required.	Acceptable	IQ

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S. No	Process Steps/Component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
Containment										
31.	Containment	Hazardous product can escape in the environment	No	It will not affect the quality of the product	EHS	The environment may get contaminated with hazardous product.	High	• Exhaust air shall be passed through wet scrubber • The risers shall be sealed to the top of the duct level. • A combination of pressure bubble and sink concept shall be used in the design. • There shall not be any opening in return duct up to AHU	Low	IQ/OQ
Building Management system										
32.	BMS	Improper installation of software	Yes	Incorrect operation	No	NA	High	Proper installation has to be ensured.	Acceptable	IQ
33.	BMS	Non compliance to 21 CFR part 11	Yes	Electronic record integrity	No	NA	Medium	Must comply the code requirement	Acceptable	IQ

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S. No	Process Steps/Component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
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34.	BMS	Malfunction	Yes	Correct function basic requirement for GMP-compliant operation	No	NA	High	• Malfunction for RH, temperature, room differential pressure, filter status shall be alarmed	Acceptable	IQ & OQ
35.	BMS	Change of program	Yes	Change of program by unauthorized persons (User access not controlled)	No	NA	Medium	• Different access levels for operations are provided • Automatic logout after pre-defined time shall be considered in the design.	Acceptable	OQ
36.	BMS	Unauthorized entry in the system	Yes	Unauthorized and unnoticed change of parameter	No	NA	Medium	• Various levels of access controls are designed	Acceptable	OQ

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S. No	Process Steps/Component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
37.	BMS	No password expiry	Yes	Basic requirement	No	NA	Low	• Periodic change of the password is designed and periodic expiry of the password is designed. • Test implementation in qualification activities, (technical control for periodical changing of passwords possible) is to be done.	Acceptable	OQ
Controlling System										
38.	HMI	Wrong language	Yes	Basic requirement	No	NA	Low	• English Language is provided.	Acceptable	OQ
39.	HMI	Insufficient data displayed	Yes	Basic requirement	No	NA	Low	• Sufficient resolution on the display is provided.	Acceptable	OQ
40.	HMI	No alarm messages	Yes	Basic requirements	No	NA	Medium	• Alarm messages on operator panel and recorder or alarm printer is designed. • Optical / acoustical alarm (display / lamp / hooter) is provided.	Acceptable	OQ

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								Mitigation Method	Residual risk level	Verification
41.	Power	Power off	Yes	Temperature, RH and differential pressure cannot be maintained	No	NA	High	Maximum acceptable power failure period is determined. SOP: Action in case major power breakdown is to be developed.	Acceptable	OQ & PQ
42.	Power	Power off to BMS system	Yes	• Alarm notification system will not work • System may lose acquired data	No	NA	Medium	BMS system is provided with uninterrupted power supply System will restore data in case of power failure.	Acceptable	OQ
Measuring Instruments										
43.	Measuring Instruments	Measuring instruments are not within defined range	Yes	Cause operational failure	No	NA	Medium	Instrument operating ranges are defined	Acceptable	OQ

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S. No	Process Steps/Component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
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44.	Measuring Instruments	Measuring instruments could not be calibrated	Yes	Operational failure	No	NA	Medium	Instruments is to be calibrated before and after installation	Acceptable	IQ & OQ
Documentation										
45.	Documentation	Critical surfaces are not tested for material of construction and test reports are not provided	Yes	Documented evidence	No	NA	High	Material test certificate must be provided	Acceptable	IQ
46.	Documentation	Instruments are not provided with calibration certificate	Yes	Documented evidence	No	NA	High	Calibration certificate to be provided	Acceptable	IQ
47.	Documentation	System is not provided with design and functional specification	Yes	Qualification requirement	No	NA	Medium	Functional and design specification must be provided	Acceptable	IQ
48.	Documentation	System is not provided with Operation and maintenance manual	Yes	Operational requirement	No	NA	Medium	O&M manual must be provided	Acceptable	IQ

FAILURE MODE EFFECT ANALYSIS FOR HEATING VENTILATION AND AIR CONDITIONING SYSTEM

S. No	Process Steps/Component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
49.	Documentation	SOP	Yes	GMP requirement	No	NA	High	SOP shall be prepared aligned with the system manual	Acceptable	IQ/OQ
50.	Documentation	Component identification	Yes	Pre-requisite for qualification	No	NA	Low	Tag No. / Labeling to be mandatory as per the Project Standard	Acceptable	IQ
51.	Documentation	Calibration not performed	Yes	Calibration for critical sensors necessary	No	NA	High	Check of instrument calibration during qualification.	Acceptable	IQ
Safety										
52.	Safety	• No Safety against fire smoke • Improper handling of system.	Yes	May lead to product contamination	EHS	• May pass the flame to all production area. • System malfunction.	High	• Fire /smoke sensor shall be provided which sense the smoke and stop the Supply and return fans. • Fire damper shall be provided in the AHU plenum • Proper training to all operating and Maintenance staff.	Acceptable	IQ &OQ

FAILURE MODE EFFECT ANALYSIS FOR HEATING VENTILATION AND AIR CONDITIONING SYSTEM

S. No	Process Steps/Component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
53.	Emergency stop	Emergency stop of the system is not possible.	No	Final air quality will not be affected.	EHS	The system cannot be switched off immediately if necessary exists.	Medium	Local operating Emergency stop switch /power off will be provided in each block system wise.	Acceptable	IQ &OQ
54.	Noise level	Noise level liberated by the system is high.	No	It will not affect the final quality of air.	EHS	Heavy noise will cause problems to the service persons	Medium	System shall be designed for noise control below 80 db.	Acceptable	IQ &OQ

9.0 Summary and Conclusion

- The risk assessment is performed to establish the design parameters of the equipment so as to meet the desired performance of the equipment i.e. HVAC System.
- The critical risks pertaining 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 at the time of accomplishment of OQ of the machine.
- To control the risk, various mitigation methods shall be verified through SOPs ,operation & maintenance manuals, and calibration certificates at respective verification points
- Based on Risk assessment, the URS shall be prepared.

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

10.0 Abbreviation

Acronym-	Definition
BMS	Building Management System
cGMP	Current Good Manufacturing Practice
db	Decibel
EHS	Environment Health and Safety
EU-GMP	European –Good Manufacturing Practice
GA	General Arrangement
GAMP	Good Automated Manufacturing Practices
GMP	Good Manufacturing Practices
HMI	Human Machine Interface
IQ	Installation Qualification
LCD	Liquid Crystal Display
MOC	Material Of Construction
OQ	Operational Qualification
O & M	Operation and Maintenance Manual
PLC	Programmable Logic Controller
RPM	Revolution per minute
SOP	Standard Operating Procedures
SS	Stainless steel
URS	User Requirement Specification