PRE RISK ANALYSIS FOR HEATING VENTILATION AND AIR CONDITIONING UNIT

RISK ASSESSMENT

REPORT BY FMEA

Product/System/Equipment	**Heating Ventilation And Air Conditioning Unit**
Risk Assessment Report No.	
Report Date	

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DOCUMENT APPROVAL:
This risk analysis study for the preapproval of report by following:

Responsibility	Department	Name	Signature	Date
Prepared by	Quality assurance			
Reviewed by	Production			
	Quality control			
	Engineering			
	Store			
	Quality assurance			
Approved by	Head-QA			

PRE RISK ANALYSIS FOR HEATING VENTILATION AND AIR CONDITIONING UNIT

1.0 Introduction

The heating ventilation and air conditioning are the technology to maintain the indoor environmental quality. Its goal is to provide thermal comfort and acceptable indoor air quality. In pharma industry HVAC is used for the product safety and to maintain the environment condition.

2.0 Objective

Objective of this report is to assess the risk associated with the heating ventilation and air conditioning unit.

3.0 Scope

Scope of this report is limited to the risk assessment associated with the heating ventilation and air conditioning unit.

4.0 Risk Assessment Approach

Risk assessment is carried out as per FMEA (Failure mode effects analysis) method.

5.0 Responsibility

Quality Assurance
Engineering
Production
Quality Control
Store

6.0 Reference Documents

1. ICH Q9-Quality Risk Management

PRE RISK ANALYSIS FOR HEATING VENTILATION AND AIR CONDITIONING UNIT

Background

……..Pharmaceuticals Limited is intended to start manufacturing facility of Tablet & Dry syrup at ……. Risk assessment is a part of corporate quality assurance. Post Quality Risk assessment of "HVAC" is done to check the system is capable of providing quality air. Company is maintaining areas as per ISO 8 in core production area

All the AHUs are qualified during the installed and prequalified as per the ISO 14644.

AHUs are installed on the service floor of the main building. AHUs are maintained with 80-95% recirculation and 5-20% fresh air supply. Fresh air supply is passed through 10 micron filter. A dedicated AHU is provided to microbiology area.

7.0 RISK RANKING PARAMETERS

7.1 Rating parameters for Severity

Effect	Scale	Description
No effect	1	No effect on output
Very slight	2	Customer not annoyed
Slight	3	Slight
Minor	4	Minor effect on performance
Moderate	5	Moderate effect on performance
Significant	6	Partial failure but operable
Major	7	Product performance severely affected, but some operability and safe
Extreme	8	Very dissatisfied, product inoperable but safe
Serious	9	Potentially hazardous effect, time-dependent failure
Hazardous	10	Hazardous effect, safety related sudden failure

7.2 Rating parameters for Occurrence

Occurrence	Scale	Description
Almost never	1	Failure unlikely; history shows no failures
Remote	2	Rare number of historical failure
Very Slight	3	Very few failures likely
Slight	4	Few failures likely

Occurrence	Scale	Description
Low	5	Occasional number of failures likely
Medium	6	Medium number of failures likely
Moderately High	7	Moderately high number of failures likely
High	8	High number of failures likely
Very High	9	Very high number of failures likely
Almost certain	10	Failure almost certain

7.3 Rating parameters for Detection control

Detection	Scale	Description
Almost certain	1	Proven detection methods with high reliability
Very High	2	Proven detection methods available
High	3	Detection tools have high chance of detecting methods
Moderately High	4	Almost certain not to detect failure
Medium	5	Detection tools have moderate chance of detecting defect
Low	6	Detection tools have a low chance of detecting failure
Slight	7	Detection tools may not detect failure
Very Slight	8	Detection tools will probably not detect failure
Remote	9	Detection tools most likely will not detect failure
Impossible	10	Failure not detected

8.0 ACCEPTANCE CRITERIA FOR RISK ASSESSMENT BY FMEA

Acceptance criteria for FMEA are as follows:

S.No.	RPN Rating	RPN Category	Action Status
1.	≥ 76	Critical	CAPA Required
2.	51 to 75	Major	CAPA Required
3.	26 to 50	Moderate	CAPA Required
4.	Up to 25	Minor	Not applicable

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

PRE RISK ANALYSIS FOR HEATING VENTILATION AND AIR CONDITIONING UNIT

9.0 PRE RISK ASSESSMENT AS PER FMEA:

Name of facility/Engineering/Equipment/Process/Operation: HVAC

S.No.	Potential Failure Mode	Potential effect (s) of failure	Severity (S)	Potential cause/ Mechanism of failure	Occurrence (O)	Current Control	Detection (D)	RPN (S x O x D)	Recommended action	Responsibility and TCD	Action Results				
											Action taken	Severity	Occurrence	Detection	New RPN
1	Required area not sufficient for HVAC system (Placement, maintenance, distribution, operation) Installation.	Area will not be suitable for proper functioning of HVAC system.	4	No or less clarity for the selection of HVAC System and required area	3	Approved lay out is in place with dimension and required area.	2	24	Current control measures are adequate	NA	NA	NA	NA	NA	NA
2	Source of air (Environmental condition, Filters) are not proper.	HVAC system cannot be Functioning effectively.	4	Inadequate knowledge and training.	2	Air source and environmental condition And filters defined in layout.	2	16	Current control measures are adequate	NA	NA	NA	NA	NA	NA
3	Required Utility (Electricity, chilled water, hot water) not available.	HVAC system Cannot be functioning.	6	No or less clarity defined for the required utility.	2	Arrangement is made to supply required utility for running of HVAC in URS.	1	12	Current control measures are adequate	NA	NA	NA	NA	NA	NA
4	Filter cleaning room is not available.	Filters cannot be cleaned and stored properly.	7	No or less clarity for the requirement of filter cleaning room.	2	Approved lay out is in place for cleaning of filters with required utilities.	1	14	Current control measures are adequate.	NA	NA	NA	NA	NA	NA

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QUALITY ASSURANCE DEPARTMENT

PRE RISK ANALYSIS FOR HEATING VENTILATION AND AIR CONDITIONING UNIT

S.No.	Potential Failure Mode	Potential effect (s) of failure	Severity (S)	Potential cause/ Mechanism of failure	Occurrence (O)	Current Control	Detection (D)	RPN (S x O x D)	Recommended action	Responsibility and TCD	Action Results				
											Action taken	Severity	Occurrence	Detection	New RPN
5	Wrong system selection in terms of Dimension, design, capacity and output (quantity) and quality of HVAC system.	Desired Quality and Quantity of air cannot be generated and distributed.	6	No or less clarity for the selection of HVAC system required for entire plant.	3	Approved lay out is in place with dimension and required area. Specification for required grade is defined in URS. Selection of vendor will be based on his expertise in HVAC system and reputed on the pharmaceutical field.	1	18	Current control measures are adequate.	NA	NA	NA	NA	NA	NA
6	Adequate safety measures are not available	Accident may happen.1) Effect on human safety. 2) Effect on product quality	10	Safety precautions are not properly defined.	2	Requirement of safety measures like generation, distribution and retention of air is defined in URS.	1	20	Current control measures are adequate.	NA	NA	NA	NA	NA	NA

PRE RISK ANALYSIS FOR HEATING VENTILATION AND AIR CONDITIONING UNIT

9.1 REVIEW OF RISK ASSESSMENT AS PER FMEA AFTER ACTION TAKEN:

Action Results					Remarks
Action Taken	Severity	Occurrence	Detection	RPN	

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10.0 RISK CONTROL MEASURES

Investigation/ findings: *(an extra sheet can be used if space is insufficient)*

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Corrective Action: *(an extra sheet can be used if space is insufficient)*

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(Sign/Date)

PRE RISK ANALYSIS FOR HEATING VENTILATION AND AIR CONDITIONING UNIT

11.0 SUMMARY AND CONCLUSION REPORT FOR RISK ASSESSMENT

Summary:……..

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Conclusion:

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12.0 FINAL REPORT APPROVAL:

The final report shall be signed after identifying all the risks and critical control parameters. All the reports or documents have been attached to the respective report (if applicable).

Signature in the block below indicates that all the control measures taken are documented and have been reviewed and found to be acceptable.

Department	Name	Designation	Signature	Date
Quality assurance				
Production				
Quality control				
Engineering				
Store				
Head-QA				