



Pharmaceutical Guidelines RISK MANAGEMENT

COMMON AHU SYSTEM

Document No: PG/RSK/001

Page 1 of 20

**Pharmaceutical Guidelines
Risk Management
System: Common AHU
Document No: PG/RSK/001**

TABLE OF CONTENTS

Sr. No.	Content	Page No.
1.0	Pre approval	3
2.0	Overview	
	Objective	4
	Scope	4
3.0	Reason for Risk Assessment	4
4.0	Team Members	4
5.0	Prerequisites	4
6.0	Description	5
7.0	Definitions and Methodology	7
8.0	Risk Execution	9
9.0	Evaluation and CAPA	
	Evaluation and CAPA of High Risk	13
	Evaluation and CAPA of Medium Risk	14
	Evaluation and CAPA of Low Risk	16
10.0	Training Record	17
11.0	Summary	18
12.0	Conclusion	18
13.0	Reference Documents	18
14.0	Abbreviation	19
15.0	Attachments	19
16.0	Post Approval	20

Pharmaceutical Guidelines

RISK MANAGEMENT

COMMON AHU SYSTEM

Document No: PG/RSK/001

Page 3 of 20

1.0 PRE-APPROVAL:

Prepared by	Designation	Signature	Date

Reviewed By	Designation	Signature	Date
HOD Production			
HOD Stores			
HOD Engineering			
Executive Quality Assurance			
Unit Head			

Approved By	Designation	Signature	Date
HOD Quality Assurance			

COMMON AHU SYSTEM

Document No: PG/RSK/001

Page 4 of 20

2.0 OVERVIEW:

2.1 Objective: The objective of this study is to provide the outline for the analysis of risk involved in Common AHU System.

2.2 Scope: The scope of this study is to provide the tools for Risk Management that can be applied to highlight the risk involved in Common AHU system.

3.0 REASON FOR RISK MANAGEMENT:

The Risk Management shall be performed, but not limited to the following cases:

- Please tick the appropriate option.
- Common AHU System ()
- Other (Please specify)

4.0 TEAM MEMBERS:

Following team members have been involved in the brain storming session of the Risk Management of Common AHU.

Date: _____ **Venue:** _____

Sr. No.	Name	Designation	Signature
1.			
2.			
3.			
4.			
5.			

5.0 PREREQUISITES:

Sr. No.	Description	Y/N/NA	Checked by	Date
1.	Anemometer	Y		
2.	Drawing (Pressure Segregation)	Y		
3.	AHU Qualification document	Y		
4.	Calibration certificates	Y		
5.	Qualification document of Dust Extractor	Y		

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COMMON AHU SYSTEM

Document No: PG/RSK/001

Page 5 of 20

Description:

Risk Management in Common AHU:

The Quality risk management of Common AHU is a systematic process for the assessment, control, communication and review of the risk.

Responsibility

Common AHU risk management activities are usually, undertaken by interdisciplinary teams. When teams are formed, they should include experts from the appropriate areas (e.g., Quality, Engineering, and Production) in addition to individuals who are knowledgeable about the HVAC risk management process.

Risk assessment

HVAC risk assessment begins with three fundamental questions.

1. What might go wrong?
2. What is the likelihood (probability) it will go wrong?
3. What are the consequences (severity)?

Risk identification addresses the “What might go wrong?” question, including the possible consequences.

Risk analysis, In some risk management tools, the ability to detect the harm (detectability) also factors in the estimation of risk.

Risk Evaluation, compares the identified and analyzed risk against given risk criteria. Risk evaluations consider the strength of evidence for all three of the fundamental questions.

The output of risk is measured in two ways:

- **Quantitatively**. In this case we have to give numerical values for risk measurement.
- **Qualitatively**. In this case we have to categorize risk into “High”, “Medium” and “Low”.

Risk Control

Risk Control includes decision making to reduce and/or accept risks.

Risk Control might focus on the following questions:

- Is the risk above an acceptable level?
- What can be done to reduce or eliminate risks?
- Are new risks introduced as a result of the identified risks being controlled?

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 Communication

Risk Communication is the sharing of information about risk and risk management between the decision makers and others. Communication need not be carried out for each and every risk acceptance.

Risk Review.

Risk Management should be an ongoing part of the quality management processes. A mechanism to review or monitor events should be implemented.

HVAC Planned events review.

E.g. Change Control, Deviations, Incidence, Drawings etc.

HVAC unplanned events review.

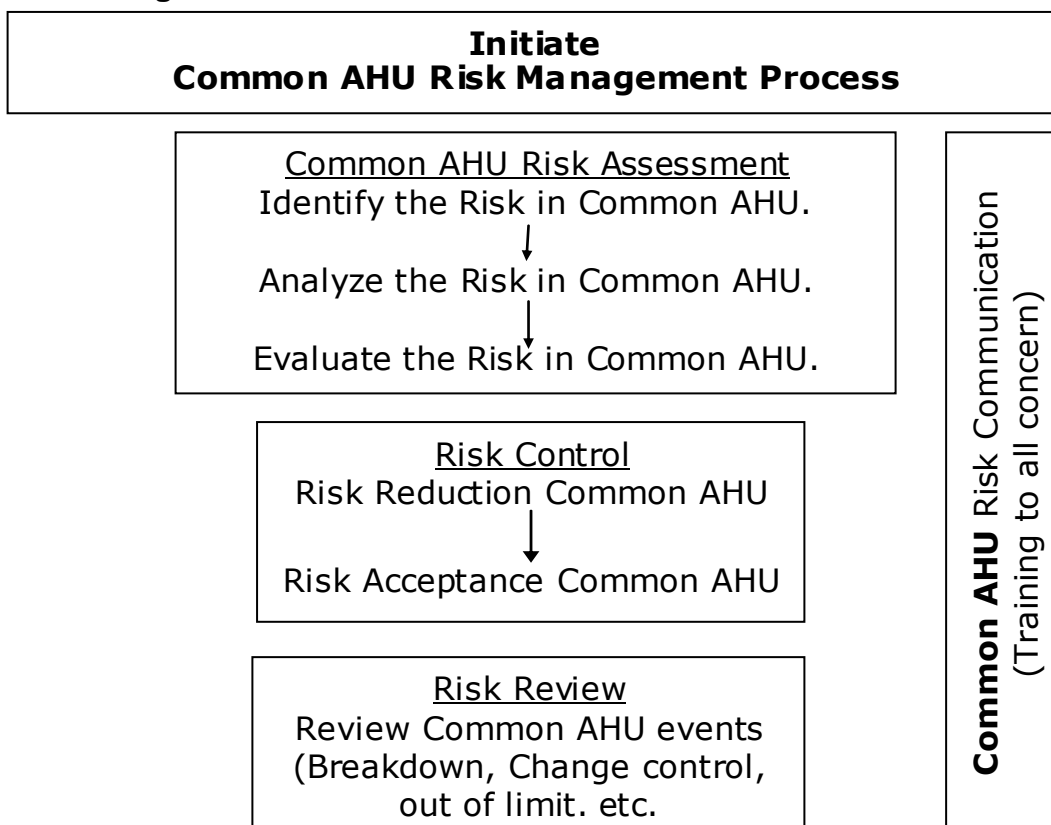
E.g. out of Limit, Break down etc.

COMMON AHU SYSTEM

Document No: PG/RSK/001

Page 6 of 20

Process Flow Diagram:



Overview of Quality Risk Management of Common AHU

Execution:

A) Common AHU Area.

1. AHU No. 1 (Blending I, Blending II, Blending III)
2. AHU No. 2 (Compression I, Compression II, Compression III)
3. AHU No. 3 (Coating I, Coating II, Coating III)
4. AHU No. 4 (Passage No. III, Tablet inspection, IPQC)
5. AHU No. 5 (Alu-Alu-I, Blister-I, Strip-I)

B) Risk in Common AHU.

- Area Contamination may be due to puncture of HEPA filter (**R001**).

Action Plan

Daily monitoring of differential air pressure across the HEPA filter.

Periodic testing of HEPA filter for integrity test.

Daily monitoring of differential air pressure in the areas (e.g. compression, coating, granulation with respect to adjacent passage)

- Chocking of HEPA filter (**R002**).

Action Plan

Daily monitoring of differential air pressure across the HEPA filter.

Daily monitoring of differential air pressure in the areas (e.g., compression, coating, granulation with respect to adjacent passage)

COMMON AHU SYSTEM

Document No: PG/RSK/001

Page 7 of 20

- HEPA integrity not as per 99.997% (**R003**).
Action Plan
 Integrity test of HEPA filter (PAO) has been carried out yearly but not limited to this criterion, if there some leakage observed we shall reconsider the integrity test.
- Cross contamination between the adjacent areas, when all AHU's are in operation (**R004**).
Action Plan
 Pressure differential maintained between the areas in order to avoid cross contamination. We have dedicated dust extractor unit for high powder generated areas. Return air recirculated through HEPA (plenum) filter.
- Cross contamination between the adjacent areas, when any AHU shut down. With respect to passage on production floor (**R005**).
Action Plan (With challenge test)
 Cross contamination verified by conducting following activity between the areas catered by common AHU.
 - Check the velocity with the help of anemometer at the return riser between the areas. Above activity done on production floor, when no production was going on. We allow positive pressure inside the area from the adjacent area by opening the door (considering the worst case) in which no pressure is maintain due to shut down of AHU. Then we place anemometer near the Return riser of next adjacent area catered with common AHU. We had not observed any reading in the next adjacent room. So, we can very well assure ourself that there is no cross contamination at the time of AHU shut down (single AHU catering different areas).
 - Check the cross contamination between the adjacent areas with the help of PAO. We generate PAO aerosol in one area near the return riser and close the door properly. In the adjacent rooms we scan with the help of PAO scanner in all the return risers. We carried above operation in the compression area, and observe that there is no PAO particle.

Hence, we conclude that there is no cross contamination during the AHU shut down (common AHU with respect to adjacent areas).
- Cross contamination between the areas, at the time of power failure (**R006**).
Action Plan.
 Cross contamination is not possible during the power failure as no AHU is in operation. Power resume within 2 minutes of failure.
 Study conducted to observe and record the temperature and humidity during the power failure. (Annexure attached)

7.0 DEFINITIONS AND METHODOLOGY:

Risk management is a activity which integrates, recognition of risk, risk assessment, developing strategies to manage it, and mitigation of risk using appropriate resources.

Severity of impact:

Identify the severity of impact of the risk of HVAC on the quality of the product. Categorize the severity of impact of risk as Critical / High / Moderate / Minor / Insignificant as defined below and put score against each risk .

Pharmaceutical Guidelines

RISK MANAGEMENT

COMMON AHU SYSTEM

Document No: PG/RSK/001

Page 8 of 20

Category	Description	Score
Critical	Very significant and having catastrophic impact on product	1
High	Significant losses and require timely addressal management intervention required.	2
Moderate	Loss of operating capability, long term of problem causes adverse effect.	3
Minor	Impact on operations and efficiency, but limited effect.	4
Insignificant	Very minor or no impact on operations and quality of operational efficiency.	5

Likelihood of impact:

Identify the likelihood of impact of risk based on the occurrence frequency and put score against each risk at step.

Category	Description	Score
Almost certain	Is expected to occur in most circumstances	1
Likely	Will probably occur in most circumstances	2
Possible	Will probably occur at some time	3
Unlikely	Could occur at some time	4
Rare	May occur in exceptional circumstances	5

Mitigation Control:

Rate the mitigation control parameter, as follows.

Category	Description	Score
Not aware	Insufficient information to adequately assess and rate the control	1
Non existent	No mitigation plans in place	2
Not effective	Mitigation plans though in place do not ensure adequate control over risk occurrence / impact.	3
Effective	Mitigation plans involve is effective against the identified risk of HVAC, although chances of occurrence minimize, but there is very less possibility of occurrence of identified risk.	4
Very Effective	Mitigation plans involve high degree of control on the operational procedure and is effective against all identified risk.	5

Calculate the total score involved for the particular risk in HVAC by adding the scores of Severity of impact, Likelihood of impact and Mitigation control.

Categorize the risk as Low risk, Medium risk or High risk, based upon the total score obtained, as follows:

RISK LEVEL	OBTAINED SCORE
HIGH RISK	3 to 6
MEDIUM RISK	7 to 11
LOW RISK	12 to 15

Upon evaluation of the risk, elaborate the methodology for the handling of risk and Corrective action, Preventive action (CAPA) plan for the identified risk.

Pharmaceutical Guidelines

RISK MANAGEMENT

COMMON AHU SYSTEM

Document No: PG/RSK/001

Page 9 of 20

8.0 RISK EXECUTION:

Severity of Impact:

Sr.No.	Risk Identification No.	Risk Involved	Quantitative Score	Qualitative Status	Remarks
1.	R001	Area Contamination may be due to puncture of HEPA filter.	1	Critical	
2.	R002	Chocking of HEPA filter	3	Moderate	
3.	R003	HEPA integrity not as per 99.997%	1	Critical	
4.	R004	Cross contamination between the adjacent areas, when all AHU's are in operation	3	Moderate	
5.	R005	Cross contamination between the adjacent areas, when any AHU shut down. With respect to passage on production floor	3	Moderate	
6.	R006	Cross contamination between the areas, at the time of power failure.	3	Moderate	Annexure Attached

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Pharmaceutical Guidelines

RISK MANAGEMENT

COMMON AHU SYSTEM

Document No: PG/RSK/001

Page 10 of 20

Likelihood of impact:

Sr.No.	Risk Identification No.	Risk Involved	Quantitative Score	Qualitative Status	Remarks
1.	R001	Area Contamination may be due to puncture of HEPA filter.	4	Unlikely Occurrence	
2.	R002	Chocking of HEPA filter	4	Unlikely Occurrence	
3.	R003	HEPA integrity not as per 99.997%	4	Unlikely Occurrence	
4.	R004	Cross contamination between the adjacent areas, when all AHU's are in operation	4	Unlikely Occurrence	
5.	R005	Cross contamination between the adjacent areas, when any AHU shut down. With respect to passage on production floor	4	Unlikely Occurrence	
6.	R006	Cross contamination between the areas, at the time of power failure.	4	Unlikely Occurrence	Annexure Attached

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Pharmaceutical Guidelines

RISK MANAGEMENT

COMMON AHU SYSTEM

Document No: PG/RSK/001

Page 11 of 20

Mitigation Control:

Sr.No.	Risk Identification No.	Risk Involved	Quantitative Score	Qualitative Status	Remarks
1.	R001	Area Contamination may be due to puncture of HEPA filter.	4	Effective Control	
2.	R002	Chocking of HEPA filter	4	Effective Control	
3.	R003	HEPA integrity not as per 99.997%	4	Effective Control	
4.	R004	Cross contamination between the adjacent areas, when all AHU's are in operation	4	Effective Control	
5.	R005	Cross contamination between the adjacent areas, when any AHU shut down. With respect to passage on production floor	4	Effective Control	
6.	R006	Cross contamination between the areas, at the time of power failure.	4	Effective Control	Annexure Attached

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Pharmaceutical Guidelines

RISK MANAGEMENT

COMMON AHU SYSTEM

Document No: PG/RSK/001

Page 12 of 20

- Identification of risk involved in HVAC.
- Analyzing the risk involved in HVAC.
- Evaluation of risk involved in HVAC.
- Mitigation of risk involved in HVAC.

Evaluation of Risk by Quantitative method and Qualitative Method.

Sr. No	Identification of Risk Involved	Analyzing the Risk	Evaluation of Risk	Risk Reduction	Quantitative Evaluation	Qualitative Evaluation	Risk Identification No.
	Description	Severity of Risk Impact	Likelihood Risk	Mitigation Plan (Control)	Total Score	Risk Category	
1.	Area Contamination may be due to puncture of HEPA filter.	1	4	4	9	Medium Risk	R001
2.	Chocking of HEPA filter	3	4	4	11	Medium Risk	R002
3.	HEPA integrity not as per 99.997%	1	4	4	9	Medium Risk	R003
4.	Cross contamination between the adjacent areas, when all AHU's are in operation	3	4	4	11	Medium Risk	R004
5.	Cross contamination between the adjacent areas, when any AHU shut down. With respect to passage on production floor	3	4	4	11	Medium Risk	R005
6.	Cross contamination between the areas, at the time of power failure.	3	4	4	11	Medium Risk	R006

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Pharmaceutical Guidelines RISK MANAGEMENT

COMMON AHU SYSTEM

Document No: PG/RSK/001

Page 13 of 20

9.0 EVALUATION AND CAPA:

EVALUATION AND CAPA OF HIGH RISK (Score 3 to 6)

Risk ID. No.	Total Score	Corrective action	Preventive action	Responsibility	Remarks

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Pharmaceutical Guidelines

RISK MANAGEMENT

COMMON AHU SYSTEM

Document No: PG/RSK/001

Page 14 of 20

EVALUATION AND CAPA OF MEDIUM RISK (Score 7 to 11):

Risk ID. No.	Total Score	Corrective action	Preventive action	Responsibility	Remarks
R001	9	Shall replace the HEPA filters	Daily monitoring of differential air pressure across the HEPA filter. Periodic testing of HEPA filter for integrity test. Daily monitoring of differential air pressure in the areas (e.g., compression, coating, granulation with respect to adjacent passage)	Engineering	
R002	11	Replace the HEPA filter	Daily monitoring of differential air pressure across the HEPA filter. Daily monitoring of differential air pressure in the areas (e.g., compression, coating, granulation with respect to adjacent passage)		
R003	9	Replace the HEPA filter	Integrity test of HEPA filter (PAO) has been carried out yearly but not limited to this criterion, if there some leakage observed we shall reconsider the integrity test.		

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Pharmaceutical Guidelines

RISK MANAGEMENT

COMMON AHU SYSTEM

Document No: PG/RSK/001

Page 15 of 20

EVALUATION AND CAPA OF MEDIUM RISK (Score 7 to 11)

Risk ID. No.	Total Score	Corrective action	Preventive action	Responsibility	Remarks
R004	11	NA	Pressure differential maintained between the areas in order to avoid cross contamination. We have dedicated dust extractor unit for high powder generated areas. Return air circulated through HEPA (plenum) filter		
R005	11	NA	Study conducted for Preventive action		
R006	11	Power resumption within 2 minutes	NA		

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Date : _____



Pharmaceutical Guidelines RISK MANAGEMENT

COMMON AHU SYSTEM

Document No: PG/RSK/001

Page 16 of 20

EVALUATION AND CAPA OF LOW RISK (Score 12 to 15)

Risk ID. No.	Total Score	Corrective action	Preventive action	Responsibility	Remarks

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Date : _____



Pharmaceutical Guidelines RISK MANAGEMENT

COMMON AHU SYSTEM

Document No: PG/RSK/001

Page no 17 of 20

10.0 TRAINING RECORD:

Date : Venue : Title :		Name of Trainer : Method of Training :		
Sr. No	Name of Employee	Designation	Signature of Trainee	Remarks
1.				
2.				
3.				
4.				
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16.				
17.				
18.				

Comments:

Verified By:

Date:



Pharmaceutical Guidelines

RISK MANAGEMENT

COMMON AHU SYSTEM

Document No: PG/RSK/001

Page no 18 of 20

11.0 SUMMARY:

12.0 CONCLUSION:

13.0 REFERENCE DOCUMENTS:

Sr. No.	Title
1.	ICH-Q9 (Risk Assessment)
2.	
3.	
4.	
5.	

COMMON AHU SYSTEM

Document No: PG/RSK/001

Page no 19 of 20

14.0 ABBREVIATION:

Sr. No.	Abbreviation	Description
1.	HVAC	Heating Ventilation and air conditioning
2.	PAO	Poly alpha olefin

15.0 ATTACHMENTS:

Sr. No.	Description
1.	AHU Drawing
2.	Pressure Differential Segregation Drawing
3.	
4.	
5.	

COMMON AHU SYSTEM

Document No: PG/RSK/001

Page no 20 of 20

16.0 POST APPROVAL:

Reviewed By	Designation	Signature	Date
HOD Engineering			
HOD Production			
HOD Stores			
Executive Quality Assurance			
Unit Head			

Approved By	Designation	Signature	Date
HOD Quality Assurance			