



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

FAILURE MODE EFFECT ANALYSIS FOR AIR HANDLING UNIT

QRA No.:

Name of Equipment: Air Handling Unit System **Date of Quality Risk Assessment:**

S. No.	Item/ Function	Potential Failure Mode (Failure mode)	Potential Effect of Failure	Potential cause/Mechanism of Effect of Failure	Current control	Reference	Severity	Occurrence	Detection	Risk Priority Number	Recommended Actions (If any)	Post Risk			
												Severity	Occurrence	Detection	Risk Priority Number
1.	Supply duct	Leakage in duct	Room Pressure not consistently maintained leads contamination of Area and product failure.	1) Supply duct is not in curve shape.	Supply duct is proper curve shape.	Qualification documents of HVAC system.	4	1	1	4	Current control measure are adequate	NA	NA	NA	NA
				2) Joints are not properly sealed	Duct leakage test performed as per SOP										
2.	Heater	Rusted Heater	Environmental conditions (RH increase, Temperature decrease) disturbed in production areas	Rusting is electrochemical corrosion of mild steel caused Rusting requires water and oxygen (Excess Moisture in air) in presence of acid and other electrolytes.	Heater with aluminum fins (having chromium, chromium prevent rusting).	Qualification documents of HVAC system.	3	2	1	6	Current control measure are adequate	NA	NA	NA	NA
3.	U drain traps of chilled water	Blockage in Condensate U Pipe	Environmental conditions (RH increase Viable count increase) disturbed in production areas leading to contamination product failure	1) U drain traps of chilled water coils slope not properly. 2) Scaling problem in drain line.	U drain traps of chilled water coils slope properly. De scaling of drain line during preventive maintenance quarterly.		4	2	1	8	Current control measure are adequate	NA	NA	NA	NA



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4.	Return riser damper	Air balancing not done between Return air duct and supply duct if Increase Differential pressure	Environmental conditions (Differential pressure) disturbed in production areas leading to contamination product failure	1) Knowledge regarding damper marking. 2) Inadequate 3) Training regarding damper setting of return duct.	Return riser damper is installed in individual return duct. Damper marking setting as per planned preventive maintenance of HVAC.		4	2	1	8	Current control measure are adequate	NA	NA	NA	NA
5.	Increase Differential pressure	Fluctuation of Differential pressure	Environmental conditions (differential pressure) disturbed in production areas leading to contamination product failure	Damper not proper adjustment and air balancing not as per design	Marking in all damper available, air balancing had done Air velocity & room pressure monitoring routinely.		4	2	1	8	Current control measure are adequate	NA	NA	NA	NA

Where: S=Severity; O=Occurrence Probability; D=Detection; Risk category 1-25 RPN is Low risk, 26-50 RPN is Medium Risk, 51-125 RPN is High Risk.

Remarks (if any): The entire above failure mode and their Severity, Occurrence, Detection rating done and found RPN No. in between 4 to 8 and Post RPN No. in between 3 to 8. Hence Risk is low detected, it's acceptable.

Quality Risk Management Team			Reviewed By Concerned Department Head Sign & Date	Approved By Head QA Sign & Date
Name	Department	Sign & Date		
	QA			
	PRODUCTION			
	ENGG.			



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QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

Name of Equipment: Air Handling Unit System

S. No.	Recommended Action	Responsible Person	Target Date of Completion
	NA	NA	NA

Verification of Action Plan:

NA

Remarks (if any): NA

Verified By
QA
Sign & Date

Approved By
Head QA
Sign & Date