RISK ASSESSMENT FOR AHU FAILURE

S.No.	Potential failure mode	Potential effects (process/ end users) or consequence	S	Contributory Factor	O	Current control Measures	D	RPN (SxOxD)	RPN Rank
1.	Inadequate performance of AHU	• Cross-contamination of product • Product failure in microbial test	5	• New equipment facility or system or any "major change in the existing equipment" • Air/energy losses may occur during air distribution through ducts. • Contamination due to air leakage when AHU is shutdown. (negative pressure may lead to contamination) • Inappropriate operation of AHU may lead to noncompliance with respect to performance requirement and frequent maintenance.	1	• HVAC validation has been done after modification / change of equipment / area as per validation master policy refer ISO 14644-4 & WHO TRS961 guidelines. • Duct leakage has been checked through smoke test and report addressed in validation report. • Duct sheet are locked with forming quality and insulated with thermacole and cladding in aluminium. • AHU unit has been operating as per SOP with control parameters monitoring and recording. • Engineering person has been trained with respect to AHU operation SOP.	1	5	Current control measures are adequate.

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2.	Integrity of HEPA filters.	• The product contaminated with dust and foreign matters i.e. Bio load in product. • Air changes per hour may be less than desired.	3	• Damage to HEPA filter during cleaning. • Manufacturing defect/installation defect in HEPA filter. • Static pressure increase at operation time. • Loss of integrity due to continuous use.	2	• HEPA filter integrity (DOP test) is checked every year. • Air velocity across HEPA filter is checked every year. • Air changes per hour are checked every year. • Daily Differential pressure is monitoring as per SOP. • Bio load monitoring is done as per SOP. • Operators are trained for operating of volume control damper. • Cleaning and cleaning frequency is done for Pre filter as per SOP. • Operators are trained for filter cleaning.	1	6	Current control measures are adequate.

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3.	Temperature and RH of processing areas goes out of limit.	• This may affect product stability. • It may increase bio load of area. • Adverse reaction due to presence of previous product particles in the room. • Uncomfortable for working in room.	3	• Malfunctioning of AHU system • Malfunction of Actuator valve in chilled water supply line. • Pressure drop of chilled water supply. • Dust accumulation on heating coil	2	• Differential pressure is recorded twice a day in processing area. • Cleaning procedure and cleaning frequency has been defined for Pre filter as per SOP. • Damper valve adjust as per required pressure by trained operator. • All ventilation and AHU has been started and stopped in correct sequence to ensure that a negative pressure is maintained during power up and power down. • Temperature and Humidity is recorded twice a day as per SOP. • Operators have been trained for the cleaning and preventive maintenance procedure of AHU & filter. • Action and alert limit is defined for temperature & humidity for production area. • Chilled water supply pressure monitoring recoded twice a day.	1	6	Current control Measure are adequate

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4.	Failure of Magnehelic gauge or Differential pressure goes out of limit	• May lead to cross contamination with other product. • Product / area failure in Microbial test	5	• Improper air balancing. • Malfunctioning of Air Handling units. • Filter chock.	1	• Doors are properly closed at operation time. • Differential pressure is recorded twice a day in processing area. • Cleaning procedure and cleaning frequency has been defined for Pre filter as per SOP. • Damper valve adjust as per required pressure by trained operator. • All ventilation and AHU has been started and stopped in correct sequence to ensure that a negative pressure is maintained during power up and power down. • Set standard operating procedure for filter cleaning is available and followed. • All the persons involved in the cleaning operation of riser filter are trained. • Differential pressure monitoring switches has been placed across filter and monitored as per SOP.	1	5	Current control measures are adequate.

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S.No.	Potential failure mode	Potential effects (process/ end users) or consequence	S	Contributory Factor	O	Current control Measures	D	RPN (SxOxD)	RPN Rank
5.	Cross contamination product	• Undesirable therapeutic effect on patient.	4	• Common AHU. • Blocking of the filter affected the differential pressure • Uncontrolled flow of air between the work area and the external area. • There is no check done to verify the air velocity and air changes per hours (ACPH)	1	• Dedicated AHU installed for separate area. • All the persons involved in the cleaning operation of riser filter are trained and periodically retrained. • Differential pressure monitoring switches has been placed across filter and monitoring twice a day. • Differential pressure is recorded twice a day. • Set standard operating procedure for filter cleaning is available and followed. • Return air to be re-circulated are pass through filtration system. • The air velocity & ACPH shall be checked by anemometer to ensure that adequate amount of air is supplied in the room and reported in validation report.	1	4	Current control measures are adequate.

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S.No.	Potential failure mode	Potential effects (process/ end users) or consequence	S	Contributory Factor	O	Current control Measures	D	RPN (SxOxD)	RPN Rank
6.	Integrity of pre filter is lost	• Unclassified air is supplied. • HEPA filter integrity may be lost.	4	• Damage during installation or subsequent use. • Damage during cleaning of pre filters or during preventive maintenance activity.	1	• HEPA Filter integrity is checked just after installation and there after every year and recorded in validation report. • Operators are trained for the cleaning and preventive maintenance procedure as per approved SOP. • Monitoring of filters is done at regular interval in order to prevent excessive filter loading (dust particles). • Cleaning and cleaning frequency is done for Pre filter as per SOP.	1	4	Current control Measures are adequate.

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S.No.	Potential failure mode	Potential effects (process/ end users) or consequence	S	Contributory Factor	O	Current control Measures	D	RPN (SxOxD)	RPN Rank
7.	Supply of unclassified air in production cubicles	• Contamination to Product. • Bio load of area may increase.	4	• Integrity of HEPA filter may be lost. • Differential pressure with adjacent area where non-classified air is supplied is out of limit. • Damage of filter during installation or subsequent use. • Damage during cleaning of Pre filters or during preventive maintenance activity.	1	• Integrity of HEPA filters is checked at the time of installation and every year. • Air velocity across HEPA filters is checked yearly once. • Differential pressures with respect to adjacent area are maintained as per SOP. • Operators are trained for the cleaning and preventive maintenance procedure. • Pressure difference is monitored daily.	1	4	Current control measures are adequate.

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S.No.	Potential failure mode	Potential effects (process/ end users) or consequence	S	Contributory Factor	O	Current control Measures	D	RPN (SxOxD)	RPN Rank
8.	Fan failure	• Inadequate air supply • Cross contamination	4	• Belt damage • Bearing damage • Power failure • Phase tripping	1	• Preventive maintenance is done as per SOP. • V belt checked quarterly for wear and tear. • Motor pully & blower pully alignment checked quarterly. • Checked abnormal sound in motor and blower bearing. • Automatic DG set for power resuming within 3 min in case of power cut. • Single phase preventer is installed in control panel to detect tripping and auto AHU off.	1	4	Current control measures are adequate.

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9.	Duct leakage	• Room condition (temperature, humidity and differential pressure) not maintained.	4	• Damage of duct	1	• Periodic inspection of duct to identified for damage, leakage and corrosion. • MOC of duct is GI. • Duct leakage has been checked through smoke test and report addressed in validation report. • Duct sheet are locked with forming quality and insulated with thermacole and cladding in aluminium.	1	5	Current control measures are adequate.
10.	Degraded operation of chillier	• Impact on process activity	5	• Refrigerant leak • Degrade compressor • Tube leak • Heat load and recovery from contamination	1	• Daily monitoring of logbook and PM of chillers has been done quarterly basis • Differential pressure monitoring for pressure difference between different rooms.	1	5	Current control measures are adequate.

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11.	Damper position tampering	• Insufficient air distribution	4	• Differential pressure not monitored	1	• Damper is inspected and cleaned periodically. • Differential pressure of respective area is monitored by production person. • Damper position is marked in supply duct and return duct. • Preventive maintenance is done as per SOP. • Damper is periodically cleaned and physically verified. • Differential pressure monitored twice a day and recorded in log.	1	4	Current control measures are adequate.
							Overall RPN	52	

Conclusion- On the basis of risk rating calculation (RPN) and evaluation of risk assessment it has been concluded that each potential failure mode of AHU Failure in manufacturing area is comes in minor category and RPN is within acceptance limit. As per above risk assessment there is no impact on product quality and operation of HVAC system in manufacturing area will be controlled by routine monitoring of control measures**.**