PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

S.No	Potential Failure Mode	Potential Effect(process/end User) or Consequences	S	Contributory Factors		O	Current Control Measures	D	RPN (SXO XD)	RPN Rank
1.	Breakdown/failure of HVAC system causing excursion of temperature, humidity and losing differential pressure between areas	• Cross contamination • Manufacturing disruption • Material and production failure • Increase in deviation situation	2	•Preventive maintenance plan implementation failure •HEPA filter integrity failure		1	• Preventive Maintenance procedure is available SOP EN/088 (Preventive Maintenance for (AHU & FCU) • HVAC Validation will be performed once a year (± 30 days) as per VMP •Routine environmental conditions monitoring plan exists and followed as per SOP QA/086 (Temperature and Humidity Monitoring) • Routine Environmental monitoring by settle plate method. • Area Restart up SOP. • Differential Pressure Monitoring SOP No. EN/095 • Precautionary Action During Failure SOP. • Temperature mapping done. • Relative Humidity/temperature/Differential pressure monitoring log book of previous year are verified and no temperature excursion observed.	2	4	- Current control measures are adequate - Risk is acceptable
2.	• Area not qualified	• Cross contamination • Product failure	3	Area not designed as per GMP and product requirement		2	• Class 5 condition is facilitate under dispensing booth	1	6	- Current control measures are adequate - Risk is acceptable
3.	• Breakdown of air compressor • Compressed air line filter integrity failure	• Contamination of products	2	• Preventive maintenance implementation plan failure		2	• Preventive maintenance plan exists and followed • Monitoring of compressed air (± 6 month) system available	1	4	- Current control measures are adequate - Risk is acceptable
4.	• Breakdown of dispensing booth • Balance calibration failure	• Cross contamination • Dispensing error • Area not qualified	2	• Preventive maintenance plan failure • Calibration schedule procedure is not available.		1	• Requalification plan for dispensing booth exists • Calibration schedule procedure is available.	1	2	- Current control measures are adequate - Risk is acceptable

S.No	Potential Failure Mode	Potential Effect(process/end User) or Consequences	S	Contributory Factors		O	Current Control Measures	D	RPN (SXO XD)	RPN Rank
05	• Uncontrolled material and man movement	• Dispensing error • Cross contamination	2	• Material information not available in Dispensing sheet • Material identification is not available • Non adherence to gowning procedure		2	• Dispensing sheet is available. • Material status label is available • Adequate gowning procedure is established.	1	4	- Current control measures are adequate - Risk is acceptable
06	Line clearance	Cross contamination Product failure	3	Inadequacy in line clearance checklist		2	Line clearance SOP and checklist exist	1	6	- Current control measures are adequate - Risk is acceptable
07	Sharing password	• Unauthorized access	3---	• Malicious intent		2	• Password protection, hence protected from unauthorized access • Computerized system validation done • Audit trial activated	1	6	- Current control measures are adequate - Risk is acceptable

S- Severity, O- Occurrence rating, D-Detection rating, RPN Risk Priority Number

- **Conclusion:**

  It can be concluded that with the existing control measures are adequate and there is no sessional variation risk on products and HVAC and being manufacturing at …….. Risk assessment done for the evaluation to In line with the current approach in GMP, risk identification done for utilities, such as HVAC systems. A science-based, comprehensive exercise of risk assessment done for used to determine risks related to possible failure of the HVAC system and AHUs (including their components and subcomponents). An appropriate risk assessment tool are used that is failure modes and effects analysis (FMEA) is selected. Controls are identified to eliminate the risks, or minimize the risk to an acceptable level. For example, the effect of the failure of one or more AHU's in the HVAC system; the failure of dust extraction systems; the failure of AHU components such as filters, heating coils, cooling coils and fans are assessed and appropriate controls SOP's are identified and SOP's are implemented.