PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

FAILURE MODE EFFECT ANALYSIS FOR ENVIRONMENTAL MONITORING PROGRAMME

S. No	Potential failure mode	Potential effects (process/ end users) or consequence	S	Contributory Factor	O	Current control Measures	D	RPN (SxOxD)	RPN Rank
Water System									
1	Failure of bio-burden in purified water used for manufacturing and final cleaning of Equipments.	• Cross-contamination of product • Product failure in microbial test	3	• Water stagnant at user point. • Not adequate slope of piping. • Sanitization frequency not validated. • Cleaning and sanitization procedure are not standard.	3	• Hot water sanitization will be carried out to gather using storage tank. • All user's point valves are sounder & zero dead leg to avoid stagnant water. • An adequate slope of piping is provided to flush the water from pipeline at the time of drainage. • Cleaning & sanitization of piping, storage tank, has been done on weekly frequency and will be set at the time of validation of water system. • CIP (clean-in-place) system provided for cleaning of RO system.	1	9	Current control measures are adequate. Risk is acceptable
Pharmaceutical ingredients									

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2.	Failure of Sampling and Testing method	• Impact on quality and efficacy of the finished product.	3	• Sampling is not done as per standard method. • Sampling tools are not validated for cleaning. • Appropriate gowning method not followed. • Plate exposure time is not validated. • Nutrition media not capable for colony growing	4	• Sampling is done as per standard procedure. • Sampling is performed by a trained and competent operator. • Sampling tools are validated for cleaning validation. • Procedure for wear protective gown at the sampling time is in place. • Plate exposure time is validated for transfer of microorganism from the air or from a surface to nutrition media. • Nutrition media is capable of growing the microorganism to visible colonies.	2	24	Current control measures are adequate.
Facility layout and design									

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3.	Improper design of building / facilities	• Cross contamination of products. • Product failure	2	• Facility qualification is not performed at the time of designing.	3	• Interior surfaces e.g. walls, floors, ceiling are as per GMP requirements like; smooth, free from cracks and open joints and design for effective cleaning. • Pipe work, ventilation and light points and other services are designed to avoid creation of recesses which are difficult to clean. • Entry and exist procedure is in place to avoid un-authorized activity in area of production, packing. • Appropriately designed air locks, pressure differentials air supply and extraction system are in place.	2	12	Current control measures are adequate.
HVAC System									

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4.	Inadequate performance of AHU	• Cross-contamination of product • Product failure in microbial test	3	• Inappropriate operation of AHU may lead to noncompliance with respect to performance requirement and frequent maintenance. • Contamination due to air leakage when AHU is shutdown. (negative pressure may lead to contamination) • New equipment facility or system or any "major change in the existing equipment"	3	• Procedure for operation of AHU unit SOP with control parameters is in place • Engineering person has been trained with respect to AHU operation SOP. • 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 aluminum. • HVAC validation has been done as per define frequency or any change of equipment / area as per validation master policy refer ISO 14644-4 & WHO TRS961 guidelines.	2	18	Current control measures are adequate.

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5	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.
Housekeeping and Sanitation									

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6.	Fail to reduce previous product residue	• Product failure • Product contamination	5	• Cleaning procedure is not adequate and defined. • Cleaning solvent is not appropriate to cleaning.	1	• Cleaning of equipment is done as per respective SOP for respective equipment. • After completion of process equipments shall be dry cleaning at shift end and wet cleaning within 24 hrs. • Cleaning validation has been performed with consider visual cleanliness, solubility criteria, therapeutic dose criteria and toxicity criteria. • Purified water is used for cleaning of equipments. • Sampling and testing has been done for final rinse / swab and water to be used for cleaning. • Person are trained to perform cleaning of equipment.	2	10	Current control measures are adequate.
Process Equipment									

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7.	Presence of Microbial contamination	• Product loss due to contamination.	3	• Sanitization procedure not defined in SOP. • Equipment hold time study not performed	2	• Sanitization procedure is defined in respective equipment cleaning SOP. • Equipment hold time study has been performed as per protocol. • Cleaned equipment shall be hold for 24 hrs after type A cleaning and for 48 hrs after type A cleaning as per validation study.	2	12	Current control measures are adequate.

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	Failure in sampling technique	• Product failure • Product contamination	5	• Sampling technique is not defined. • Drug residue is not dissolved in swabbing solvent. • Sampling technician not trained.	1	• Rinse and swab sampling method has been defined in cleaning validation master plan (Doc No…..). • Hard to clean area of equipment has been consider for cleaning validation sampling. • Swabbing solvent used for sampling as per product residue solubility. • Swab area has been considered to calculate acceptance limit (MAR value). • Training given to concern for swab and rinse sampling during cleaning validation. • Final rinse of equipment has been tested for pH, TOC, conductivity, MAR/ml and microbial bio burden.	1	5	Current control Measure are adequate
Manufacturing personnel									

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8.	Improper Gowning	• Product contamination • Cross contamination	2	• Man movement is not controlled in production area. • Protective gowning is deficient. • Standard written gowning procedure is not available. • All personnel are not trained for hygiene. • Health examination is not performed for all personnel.	3	• Standard written procedure for proper gowning, man and material movement is in place • Persons are trained to wear protective gear as per requirements. • SOP for entry and exit procedure is in place. • All personnel are trained initially and continuing training, including hygiene instructions. • All personnel, prior to and during employment as appropriate, should undergo health examination as per SOP.	2	8	Current control measures are adequate.
							Overall RPN		

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

Conclusion- On the basis of risk rating calculation (RPN) and evaluation of risk assessment it has been concluded that the each potential failure mode of environmental monitoring for swab sample of equipment is comes in minor category and RPN is within acceptance limit. As per above risk assessment there is no impact on product quality with bio load and environmental monitoring will be perform as per current practice.