PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

Department:	**Quality Assurance**		**Date:**
Risk Assessment Title:	**Risk assessment on cross contamination in the existing manufacturing facility**		**Risk Assessment No.**
Team Members:			

S.No.	Potential failure mode	Potential effects or consequence	S	Contributory Factor	O	Current control Measures	D	RPN (SxOxD)	Additional action required Yes/No
1.0	**Mixups**								
1.1	**Facility design Flow**								
	• Improper design of building / facilities	• Cross contamination of products. • Product failure	4	• Qualification of facility is not meeting the GMP requirement. • Men and material flow is not adequate.	1	• Interior surfaces e.g. walls, floors, ceiling are complying GMP requirements like; smooth, free from cracks and no open joints and are designed for effective cleaning. • Pipe work, ventilation light points and other services are designed to avoid creation of recesses which are difficult to clean. • Entry and exit 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	8	No, Current control measures are adequate.
1.2	**Line clearance and Labeling**								

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	• Inadequate verification of labeling of raw material as well as in process material	• Product Failure	4	• Inadequate training. • Standard operating procedure is not defined.	1	• Personnel are trained to follow line clearance procedure before to start any activity. • Standard operating procedure for labeling at different stages is in place.	1	4	No, Current control measures are adequate.
2.0	**Mechanical Transfer**								
2.1	**Personnel and material movement**								
	• Improper flow of personnel and material from common corridor.	• Product contamination. • Market complaint. • Product Failure. • Regulatory observation	5	• Containment program for manufacturing area to common corridor is not adequate. • Entry of personnel in core manufacturing area through air locks/change room is not defined. • Pressure	2	• SOP for entry exit procedure is in place. • Standard written procedure for proper gowning, man and material movement is in place • Persons are trained to wear protective gear as per requirements. • Air locks for entry in core manufacturing area are appropriately designed. • Pressure differentials. air supply and dust extraction system is in place.	3	30	Yes,Containment plan to avoid the cross contamination through interlock system to be introduced.

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				differentials system for classified area is not defined.					
2.2	**Gowning Procedure**								
	• Improper Gowning	• Product contamination • Cross contamination	4	• 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	1	• 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 periodic training, including hygiene instructions are provided. • All personnel, prior to and during employment are	1	4	No,Current control Measure are adequate

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				performed for all personnel.		tested for their health as per SOP.			
3.0	**Air borne Transfer**								
	• Presence of Microbial contamination	• Product loss due to contamination. • Market complaint • Adverse reactions	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 and is validated. • Cleaned equipment shall be held for 24 hrs after type A cleaning and for 48 hrs after type B cleaning as per validation study.	1	6	No,Current control measures are adequate.
4.0	**Retention**								
4.1	**Inadequate Cleaning Procedure**								
	• Failure in sampling technique	• Product failure • Product	5	• Sampling technique is not	1	• Rinse and swab sampling method have been defined in cleaning validation master	1	5	No, Current control Measure

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		contamination		defined. • Drug residue is not dissolved in swabbing solvent. • Sampling technician not trained.		plan. • Hard to clean areas of equipment have been considered for cleaning validation sampling. • Swabbing solvent used for sampling as per product residue solubility study. • Swab area has been considered to calculate acceptance limit (MAR value). • Training given to concerned 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.			are adequate

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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 Cross Contamination 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 Cross Contamination Control in manufacturing area will be controlled by routine monitoring of control measures.