PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

Risk Assessment for Cross Contamination

Subject:								**Department:**	
FMEA Document No.								**Date:**	
S.No.	**Perceived Failure Mode**	**Potential Effect (Process/ End users or consequences)**	**S**	**Potential causes**	**P**	**Current control measures**	**D**	**RPN (SxPxD)**	**RPN category**
Receipt of Materials:									
1.	Probability of Mixing of API and excipients due to receiving of damaged consignment (due to breakage of containers, accident, during staggering of raw material containers in the cargo)	Serious contamination issue which impacts the quality and safety of materials due to ignorance of this arrived condition. Contamination of facility due to receiving of damaged consignment. Contamination of personal, area, garments, utensils due to receiving of damaged consignment of API and excipient.	5	Ware house personal responsible to receive the damaged consignment without taking precaution, is unaware regarding the contamination concern arrived due to handling of damaged API and Excipient Container. There is no any procedural control regarding the receiving of starting material if received in damaged containers. There is no any procedural control regarding the preventive measures	3	Procedures regarding special precautions to be taken at the time of receiving of damaged container of materials has been mentioned the respective standard operating procedure. Training has been provided to the all warehouse personal regarding the special precautions to be taken at the time of receiving of damaged container of starting material, which may arise serious health contamination aspect which may arise due to unsafe handling of starting material.	1	15	Minor

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				shall be taken when the damaged consignment of the material received.					
Man and Material Movement:									
2.	Personnel may enter into the warehouse/ finished goods and other applicable areas. Personals working in the Engineering and other area may come in the core processing area.	Unrestricted movement of manpower without proper training regarding serious cross contamination and improper change over (gowning) procedure may cause serious cross contamination. Unrestricted movement of manufacturing personals (Staff, operator and workers) without	5	There is no any procedural control regarding restricted movement of personal into manufacturing area and core processing area. Training regarding serious cross contamination has not been provided to personals for entry into warehouse/core manufacturing area.	3	SOP of movement of personal movement in all the areas area available with colour coding. Training on the gowning procedure in the warehouse and other core manufacturing areas is available.	1	15	Minor

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		proper training regarding serious cross contamination and improper change over (secondary gowning) procedure before entering into core manufacturing area.							
Product Contamination and Quality Issue									
3.	Product contamination due to manufacturing of product into uncontrolled area. Product contamination due to usage of compressed air and water which is not qualified.	Serious cross contamination issues in the product which affect the safety, efficacy of the product may compromise.	5	Product contamination due to manufacturing of product into uncontrolled area. Product contamination due to usage of compressed air and water which is not qualified.	3	Product manufacturing is being carried out into controlled area with the provision of terminal HEPA including sampling and dispensing of starting and primary packing material. Qualified compressed air is being used where ever compressed air comes in the contact of product. Cleaning validation of the worst	1	15	Minor

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	Product contamination due to unavailability of Cleaning Validation of the worst molecule. Product Contamination due to unavailability of Line clearance Procedure. Product contamination due to unavailability of handling of any hazardous material. Product contamination due to unavailability of Equipment and area cleaning procedure.			Product contamination due to unavailability of Cleaning Validation of the worst molecule. Product Contamination due to unavailability of Line clearance Procedure. Product contamination due to unavailability of handling of any hazardous material. Product contamination due to unavailability of Equipment and area cleaning procedure. Product contamination due to unavailability of Environmental condition.		case molecule is available having the least LD_{50}. The identified worst molecule LD_{50} is much lesser than the general corticosteroids LD_{50} provided by material manufacturer (LD_{50} 4g/kg for all three corticosteroid mentioned in MSDS provided by manufacturer) Gowning procedure is available which is applicable for all the molecules handling in the manufacturing premises. No separate gowning is recommended for handling of general steroids specified by API manufacturer. Line clearance procedure is available. Equipment Cleaning Procedure is available. Environmental Monitoring procedure is available. Area cleaning and disinfection procedure is available.			

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				Product Contamination due to unavailability of area cleaning procedure.					

QRM Team: **Warehouse:** **Production:** **Engineering:** **Plant Head:** **Quality Assurance:**

S – Severity rating, P – Probability rating, D – Detection rating, RPN – Risk Priority Number

Conclusion: All the required control is available to avoid the cross contamination concern in the manufacturing of Ointment/ Powders (Internal and External) and Liquids for internal use.