PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

FAILURE MODE EFFECT ANALYSIS FOR SAMPLING OF EXTERNAL PREPARATIONS

S. No.	Item / Function	Potential Failure Mode	Potential Effect of Failure (Effect)	Potential Cause/ Mechanism of Failure	Current Control	Reference	Risk with Current control Measure				Recommended Actions (if any)	Risk after control measure			RPN (S*O*D)
							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
1.	**Raw material Sampling**	Probability of use of Un-cleaned garments	Product Failure & mix-up chances	➢ Procedure is not available for Garments cleaning Garments cleaning are performed by untrained personnel. ➢ Garments Storage Cabinets are not provided for Storage of Garments	➢ Cleaning Procedure is available. Cleaning is performed by trained personnel. ➢ Storage Cabinets are provided for storage of garments.	SOP	4	1	3	12	NA	NA	NA	NA	NA
		Probability of mix up of material after Sampling	Contamination and Product failure	➢ Proper Status of Labeling is not done in each container of material. ➢ Material transfer procedure is not available. ➢ Proper storage condition not followed. ➢ Unskilled/Untrained person performing Sampling. ➢ Material transfer in unsafe manner. ➢ Unclean Tools used for Sampling.	➢ All containers of materials properly identified by status label. ➢ SOP is available for Raw material sampling and transfer. ➢ Provision for controlled storage condition is available. ➢ Untrained/Unqualified personnel is not allowed in the area. ➢ SOP is available for sampling tools cleaning	SOP Temperature mapping data	1	3	4	12	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
	Raw material Sampling			➢ RLAF not clean properly and Pressure Differential not in Limit. ➢ Weighing Balances are not clean.	➢ Line clearance procedure followed before start of sampling procedure.										
		Personnel Safety during Sampling	Contamination of raw material and Effect on Human Health	➢ Proper gowning procedure is not followed. ➢ Safety devices are not available. ➢ Unskilled/untrained person performing Sampling. ➢ Activity is performed by without supervision of senior person.	➢ Provision of Secondary Change Room with secondary gowning including Head gear, Body suit, and booties to avoid contamination from persons available. ➢ Safety devices are available i.e. PPE (personnel protective equipments), Gloves, mask, goggles, etc required safety devices are provided. First aid facility is provided in case of any miss happening. ➢ Untrained person is not allowed to work in sampling area. ➢ List of Authorized personnel is displayed in all area.	SOP Safety manual	1	1	4	4	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
	Raw material Sampling				➢ All activity is performed in presence of senior/experienced chemist.										
		Contamination & Cross Contamination	Product Failure	➢ In adequate cleaning ➢ Area not qualified. ➢ HVAC is not qualified. ➢ Procedure for area cleaning is not available & followed. ➢ Procedure is not available for cleaning schedule of area. ➢ Pressure differential of area is not maintained & monitored in regular intervals. ➢ Untrained / Unqualified personnel are allowed in the area.	➢ Proper cleaning & sanitization procedure are followed. ➢ HVAC & area are previously qualified. ➢ Validation cleaning procedure is available, followed & documented. ➢ Procedure is available & followed for cleaning schedule of area ➢ Pressure differential of the area is maintained, monitored at defined frequency. ➢ Untrained/Unqualified personnel is not allowed in the area. ➢ All activity is performed by trained personnel.	SOP	4	1	2	8	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
	Raw material Sampling			➢ Cleaning is performed by untrained personnel. ➢ Dedicated area is not provided for Storage of Cleaned sampling tools. ➢ Separate Washing Area is not provided. ➢ Dedicated AHUs is not provided for all the area. ➢ Procedure is not available for AHU cleaning & filter cleaning ➢ Gowning procedure is not available & not followed. ➢ Unidirectional men material movement / Flow are not provided. ➢ Pictorial for gowning procedure are not displayed in respective area.	➢ Dedicated area is provided for Storage of Cleaned Sampling tools. ➢ Separate Washing Area is provided. ➢ Dedicated AHUs is provided for all the store area. ➢ Procedure is available for AHU cleaning & filter cleaning ➢ Gowning procedure is available & followed. ➢ Unidirectional Men Material Movement / Flow are provided. ➢ Pictorial for gowning procedure are displayed in respective area. ➢ Procedure is available for Line clearance of sampling area.										

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
				➢ Procedure is not available for Line clearance of sampling area. ➢ Procedure is not available for cleaning of AHU & equipment filter ➢ Two different products sampled at a time.	➢ Procedure is available for cleaning of AHU & equipment filter ➢ Only single product sampled at a time.										

Note: Action shall be taken if Risk Priority Number is more than 64.

Where: S=Severity; O=Occurrence Probability; D=Detection

Remarks (if any):

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Quality Risk Management Team			Reviewed By Head Operations Sign & Date	Approved By Head QA Sign & Date
Name	Department	Sign & Date		

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QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

Name of Facility / Equipment / Utility / System / Activity / Procedure / Unit Operation:	Sampling (External Preparation)

S.No.	Recommended Action	Responsible Person	Target Date of Completion

Verification of Action Plan:

All the above agreed actions completed, Not Completed.

(*incase any recommendations Not completed, to be tracked through CAPA System)

Remarks (if any):

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Verified By
QA
Sign & Date

Approved By
Head QA
Sign & Date