



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

FAILURE MODE EFFECT ANALYSIS FOR SAMPLING (LIQUID INJECTION)

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	
	material Sampling			<ul style="list-style-type: none"> ➤ Unclean Tools used for Sampling. ➤ RLAF not clean properly and Pressure Differential not in Limit. ➤ Weighing Balances are not clean. 	<ul style="list-style-type: none"> ➤ Material of Drum kept separate on different-different pallets. ➤ SOP for Sampling Tools cleaning is available. ➤ Line clearance procedure followed before start of Sampling procedure. 										
		Personnel Safety during Sampling	Contamination of raw material and Effect on Human Health	<ul style="list-style-type: none"> ➤ Proper gowning procedure is not followed. ➤ Safety devices are not available. ➤ Unskilled/untrained person performing Sampling. 	<ul style="list-style-type: none"> ➤ 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. 	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			<ul style="list-style-type: none"> ➤ Activity is performed by without supervision of senior person. 	<ul style="list-style-type: none"> ➤ List of Authorized personnel is displayed in all area. ➤ All activity is performed in presence of senior/experienced chemist. 										
	Raw material Sampling	Contamination & Cross Contamination	Product Failure	<ul style="list-style-type: none"> ➤ 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. ➤ Cleaning is performed by 	<ul style="list-style-type: none"> ➤ 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. 	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	
				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. ➤ Procedure is not available for Line clearance of sampling area.	➤ All activity is performed by trained personnel. ➤ Dedicated area is provided for Storage of Cleaned dispensing 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										



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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
				<ul style="list-style-type: none"> ➤ Procedure is not available for cleaning of AHU & equipment filter ➤ Two different products sampled at a time. 	<ul style="list-style-type: none"> area. ➤ 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.



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

Remarks (if any):

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 (Liquid Injection)
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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):

Verified By
QA
Sign & Date

Approved By
Head QA
Sign & Date