



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

FAILURE MODE EFFECT ANALYSIS FOR DISPENSING (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	
1.	Raw Material Dispensing	Probability of use of Un-cleaned garments	Product Failure & mix-up chances	<ul style="list-style-type: none"> ➤ Procedure is not available for Garments cleaning Garments cleaning are performed by untrained personnel. ➤ Garments Storage Cabinets are not provided for Storage of Garments ➤ Garments cabinet is not Qualified 	<ul style="list-style-type: none"> ➤ Cleaning is performed by trained personnel. Cleaning Procedure is available. ➤ Storage Cabinets are provided for storage of garments. ➤ HEPA filter is provided in garments storage cabinets. ➤ Garments cabinet is previously qualified 	SOP	2	1	4	8	NA	NA	NA	NA	
		Probability of wrong weight of raw material	Product does not complies with specification	<ul style="list-style-type: none"> ➤ If weighing balance is not calibrated. ➤ Proper Weighing is not performed. ➤ Verification activity is not performed 	<ul style="list-style-type: none"> ➤ Calibrated weighing balance is used for weighing, verification of raw materials Verification of status label is displayed on every weighing balance. ➤ Daily verification and monthly calibration is in practice. ➤ Proper line clearance is followed & calibration of weighing balance is also part of line clearance. 	SOP	2	1	4	8	NA	NA	NA	NA	



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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
	Raw Material Dispensing				<ul style="list-style-type: none"> ➤ Weighing activity is performed in the presence of QA & Production Personnel. 										
		Probability of mix up of material after Dispensing	Contamination and Product failure	<ul style="list-style-type: none"> ➤ Proper Status of Labeling is not done in each container of material. ➤ Material transfer procedure is not available. ➤ Container of Raw material are not segregated in staging area ➤ Proper storage condition not followed. ➤ Unskilled/Untrained person performing Dispensing. ➤ Material transfer in Unsafe manner. ➤ Unclean Tools used for Dispensing. ➤ RLAFF not clean properly and Pressure Differential 	<ul style="list-style-type: none"> ➤ All containers of materials properly identified by status label. ➤ SOP is available for transfer of dispensed material. ➤ Staging room is provided for storage of dispensed material and kept in Separate Pallets with proper status label. ➤ Provision for controlled storage condition is available. ➤ Only Trained/Skilled person performing dispensing. ➤ Authorized person entry allowed on staging area and proper lock & key to be done for entry in staging area ➤ SOP for cleaning of Dispensing Tools is available. 	SOP	1	3	4	12	NA	NA	NA	NA	



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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
	Raw Material Dispensing			not in Limit. ➤ Weighing Balances are not clean.	➤ Line clearance procedure followed before start the Dispensing										
		Personnel Safety during dispensing	Effect on Human Health	➤ Proper gowning procedure is not followed. ➤ Safety devices are not available. ➤ Emergency switch are not provided in machine. ➤ Trained personnel are not available in the area. ➤ Activity is performed by without supervision of senior person. ➤ Machine is not covered by safe guard.	➤ Provision of Secondary Change Room before entry in dispensing Area. Gowning procedure are provided and followed. ➤ 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 dispensing area. ➤ List of Authorized personnel is displayed in all area. ➤ All activity is performed in presence of senior/experienced chemist. Personal involved in	SOP Safety manual SOP	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 Dispensing				<p>manufacturing are qualified</p> <ul style="list-style-type: none"> ➤ All machine and utility are covered & safe guards are provided for all machine & emergency switch also provided. 										
		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. ➤ Validated Cleaning Procedure is not available. ➤ Pressure differential of area is not maintained & monitored in regular intervals. 	<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. ➤ Validated Cleaning Procedure is available ➤ Pressure differential of the area is maintained, monitored at defined frequency. 	SOP Area Qualification Protocol	4	1	4	16	NA	NA	NA	NA	



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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
	Raw Material Dispensing			<ul style="list-style-type: none"> ➤ Untrained / Unqualified personnel are allowed in the area. ➤ Cleaning is performed by untrained personnel. ➤ Dedicated area is not provided for Storage of Cleaned dispensing 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 	<ul style="list-style-type: none"> ➤ Untrained / Unqualified personnel are not allowed in the area. ➤ All activity is performed by trained personnel. ➤ Dedicated area is provided for Storage of Cleaned dispensing tools. ➤ Separate Washing Area is provided. ➤ Dedicated AHU's 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 										



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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
				displayed in respective area. ➤ Procedure is not available for Line clearance of dispensing area. ➤ Procedure is not available for cleaning of AHU & equipment filter. ➤ Two different products dispensed at a time.	respective area. ➤ Procedure is available for Line clearance of dispensing area. ➤ Procedure is available for cleaning of AHU & filter ➤ Only single product dispensed 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:	Dispensing (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