PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR DISPENSING OF OSD

Reference Document No.: | **Risk Assessment No.:** .....

Name of Facility / Equipment / Utility / System / Activity / Procedure / Unit Operation for: Dispensing (OSD)	**Date Of Quality Risk Assessment:**

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	➢ 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 is performed by trained personnel. Cleaning Procedure is available. ➢ Storage Cabinets are provided for storage of garments.	SOP	2	1	4	8	NA	NA	NA	NA	NA
		Probability of wrong weight of raw material	Product does not complies with specification	➢ If weighing balance is not calibrated. ➢ Proper Weighing is not performed. ➢ Verification activity is not performed	➢ 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. ➢ Weighing activity is	SOP	2	1	4	8	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
					performed in the presence of QA &Production Personnel.										
	Raw Material Dispensing	Probability of mix up of material after Dispensing	Contamination and Product failure	➢ 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. ➢ RLAF not clean properly and Pressure Differential not in Limit. ➢ Weighing Balances are not clean.	➢ 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. ➢ Demarcation already done for placing more than one batch in staging area for segregation of batches. ➢ Provision for controlled storage condition is available. ➢ Authorized person entry allowed on staging area and proper lock & key to be done for entry in staging area ➢ Line clearance procedure followed before start the Dispensing	SOP	1	3	4	12	NA	NA	NA	NA	NA
		Personnel Safety during dispensing	Effect on Human Health	➢ Proper gowning procedure is not followed.	➢ Provision of Secondary Change Room before entry in dispensing Area. Gowning procedure are provided and	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			followed. ➢ Safety devices are not available. ➢ Trained personnel are not available in the area. ➢ Activity is performed by without supervision of senior person. ➢ Machine is not covered by safe guard.	➢ 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 manufacturing are qualified ➢ All machine and utility are covered & safe guards are provided for all machine & emergency switch also provided.	SOP Safety manual									
		Contamination & Cross Contamination	Product Failure	➢ In adequate cleaning ➢ Area not qualified. ➢ HVAC is not qualified.	➢ Proper cleaning & sanitization procedure are followed. ➢ HVAC & area are previously qualified.	SOP	4	1	4	16	NA	NA	NA	NA	NA

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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	
	Raw Material Dispensing			➢ 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. ➢ 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	➢ 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 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 AHUs is provided for all the store area. ➢ Procedure is available for AHU cleaning & filter cleaning	Area Qualification Protocol									

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
	Raw Material Dispensing			➢ 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 dispensing area. ➢ Procedure is not available for cleaning of AHU & equipment filter ➢ Two different products dispensed at a time.	➢ 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 dispensing area. ➢ Procedure is available for cleaning of AHU & filter ➢ Only single product dispensed at a time.										

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Reference Document No.:	Risk Assessment No.: …….

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:	Dispensing (OSD)

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