



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR DISPENSING OF EXTERNAL PREPARATIONS

Reference Document No.:

Risk Assessment No.:

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

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	<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. 	<ul style="list-style-type: none"> ➤ 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	
		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. ➤ Weighing activity is performed in the presence of QA & Production Personnel. 	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			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.	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.										

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 (External Preparation)
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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