

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	Potential Effect	Potential Cause/ Mechanism	Current Control	Reference	Risk with Current control Measure		control Measure Actions			ctions control		er	RPN (S*O*D)
		Mode	of Failure (Effect)	of Failure			S	0	D	Risk Priority Number	(if any)	S	easure O	D	
		Probability of use of	Product Failure &	➤ Procedure is not available for Garments cleaning	➤ Cleaning is performed by trained personnel.	SOP				(S*O*D)					
		Un-cleaned garments	mix-up chances	Garments cleaning are performed by untrained personnel. Garments Storage Cabinets are not provided for Storage of Garments.	Cleaning Procedure is available. Storage Cabinets are provided for storage of garments.		2	1	4	8	NA	N A	NA	NA	NA
1.	Raw Material Dispensing	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 performed in the presence of QA & Production Personnel. 	SOP	2	1	4	8	NA	N A	NA	NA	NA



QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR DISPENSING OF EXTERNAL PREPARATIONS

Reference Document No.: Risk Assessment No.:

S.	Item /	Potential	Potential	Potential Cause/	Current	Reference	D:	ek w	vith (Current	Recommended	D:	sk afte	r	RPN								
No.	Function	Failure	Effect	Mechanism	Control	Actor circ	Risk with Current control Measure		Actions		sk aru ontrol	-1	(S*O*D)										
		Mode	of Failure	of Failure															(if any)	me	easure		Ì
			(Effect)				S	0	D	Risk		S	0	D									
										Priority													
										Number (S*O*D)													
		Probability	Contaminati	➤ Proper Status of Labeling	➤ All containers of materials					(B C D)													
		of mix up	on and	is not done in each	properly identified by status	SOP																	
		of material	Product	container of material.	label.																		
		after	failure	➤ Material transfer	➤ SOP is available for transfer																		
		Dispensing		procedure is not available.	of dispensed material.																		
				Container of Raw material	➤ Staging room is provided for																		
				are not segregated in	storage of dispensed material																		
				staging area	and kept in Separate Pallets																		
					with proper status label.																		
				➤ Proper storage condition	➤ Provision for controlled																		
				not followed.	storage condition is available.							NT											
	Raw			➤ Unskilled/Untrained	➤ Only trained /skilled person		1	3	4	12	NA	N A	NA	NA	NA								
	Material			person performing	performed dispensing.							Λ											
	Dispensing			Dispensing.																			
				➤ Material transfer in unsafe	Authorized person entry																		
				manner.	allowed on staging area and																		
				➤ Unclean Tools used for	proper lock & key to be done																		
				Dispensing.	for entry in staging area																		
				➤ RLAF not clean properly	Line clearance procedure																		
				and Pressure Differential	followed before start the																		
				not in Limit.	Dispensing																		
				➤ Weighing Balances are																			
		Personnel	Effect on	not clean.	➤ Provision of Secondary																		
		Safety	Human	➤ Proper gowning procedure is not followed.	Change Room before entry in	SOP																	
		during	Health	Safety devices are not	dispensing Area. Gowning							N											
		dispensing		available.	procedure are provided and		1	1	4	4	NA	A	NA	NA	NA								
				availaute.	followed.																		
					Tonowed.																		



QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR DISPENSING OF EXTERNAL PREPARATIONS

Reference Document No.: Risk Assessment No.:

S. No.	Item / Function	Potential Failure Mode	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference	Risk with Current control Measure						Recommended Actions (if any)	co	sk afte ontrol easure		RPN (S*O*D)
			(Effect)				S	0	D	Risk Priority Number (S*O*D)		S	0	D			
				Emergency switch are not provided in machine.	➤ 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.	Safety manual											
				Trained personnel are not available in the area.	 Untrained person is not allowed to work in dispensing area. List of Authorized personnel is displayed in all area. 	SOP											
	Raw Material Dispensing			Activity is performed by without supervision of senior person.	➤ All activity is performed in presence of senior/experienced chemist. Personal involved in manufacturing are qualified												
				➤ Machine is not covered by safe guard.	➤ All machine and utility are covered & safe guards are provided for all machine & emergency switch also provided.												
		Contaminat ion & Cross Contaminat ion	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	N A	NA	NA	NA		



QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR DISPENSING OF EXTERNAL PREPARATIONS

Reference Document No.: Risk Assessment No.:

S. No.	Item / Function	Potential Failure Mode	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference		Risk with Current control Measure		Recommended Actions (if any)	co	sk afte ontrol easure		RPN (S*O*D)	
		Mode	(Effect)	of Fundre			S	0	D	Risk Priority Number (S*O*D)	(ii dily)	S	0	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 ➢ Gowning procedure is not 	 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. 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 Gowning procedure is 	SOP Area Qualification Protocol									



QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR DISPENSING OF EXTERNAL PREPARATIONS

Reference Document No.: Risk Assessment No.:

								322 2 (31)								
S. No.	Item / Function	Potential Failure Mode	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference	Risk with Current control Measure			Recommended Actions (if any)	co m	sk afte ontrol easure		RPN (S*O*D)		
			(Effect)				S	0	D	Risk Priority Number (S*O*D)		S	0	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.



QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR DISPENSING OF EXTERNAL PREPARATIONS

Reference Document No.:	Risk Assessment No.:
Where: S=Severity; O=Occurrence Probability; D=Detection	
where. 5-5everity, 6-5ecurrence riobability, D-Detection	
Remarks (if any):	

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



QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR DISPENSING OF EXTERNAL PREPARATIONS

Reference Document No.:	Risk Assessment No.:
-------------------------	----------------------

	QUALITY RISK ASSESSEMENT AND	MITIGATION SUMMARY REPORT	
Name of Facility / E	Equipment / Utility / System / Activity / Procedure / Unit Operation:	Dispensing (External Preparation)	
S.No.	Recommended Action	Responsible Person	Target Date of Completion
	eed actions completed, Not Completed. nmendations Not completed, to be tracked through CAPA System)		
Remarks (if any)	:		
T7 101 175			
Verified By QA		Approved I Head QA	
Sign & Date		Sign & Da	