

QUALITY ASSURANCE DEPARTMENT

	of Failure	Mechanism of Failure	Current Control		Risk with Current control Measure				control Measure		control Measure				Risk after control measure			RPN (S*O*D)
	(Effect)				S	o	D	Risk Priority Number (S*O*D)		S	o	D						
	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 Procedure is available. Cleaning is performed by trained personnel. Storage Cabinets are provided for storage of garments. 	SOP	4	1	4	16	NA	NA	NA	NA	NA					
Probability of mix up of material after Sampling	Contamination and Product failure	is not done in each container of material. > Material transfer procedure is not available. > Container of Raw material are not segregated > Proper storage condition not followed. > Unskilled/Untrained person performing Sampling. > Material transfer in unsafe	 All containers of materials properly identified by status label. SOP is available for Raw material sampling and transfer. Staging room is provided for storage of sampled material and kept in Container with proper status label. Provision for controlled storage condition is available. Untrained/Unqualified personnel is not allowed in 	SOP Temperature mapping data	1	3	4	12	NA	NA	NA	NA	NA					
	of use of Uncleaned garments Probability of mix up of material after Sampling	Probability of use of Uncleaned garments Probability of mix-up chances Probability of mix up of material after Sampling Contamination and Product failure	Probability of use of Uncleaned garments Probability of mix up of material after Sampling Proper Status of Labeling is not done in each container of material. Material transfer procedure is not available. Proper Status of Labeling is not done in each container of material. Material transfer procedure is not available. Proper Status of Labeling is not done in each container of material. Material transfer procedure is not available. Proper Status of Labeling is not done in each container of material. Material transfer procedure is not available. Proper Status of Labeling is not done in each container of material. Material transfer procedure is not available. Proper Status of Labeling is not done in each container of material. Proper storage condition not followed. Proper storage condition not followed. Proper storage condition not followed. Punskilled/Untrained person performing Sampling. Material transfer in unsafe	Probability of use of Uncleaned garments Probability of use of Uncleaned garments Probability of mix up of material after Sampling Propability of Garments cleaning are performed by untrained personale. Proper Status of Labeling is not done in each container of material. Proper Status of Labeling is not done in each container of material. Proper Status available. Proper Status of Labeling is not done in each container of material. Proper Status available. Proper Status of Labeling is not done in each container of material. Proper storage condition not followed. Proper storage condition not followed. Proper storage condition is available. Provision for controlled storage condition is available. Provision for controlled storage condition is available. Provision for controlled storage condition is available. Puntrained/Unqualified personnel is not allowed in	Probability of mix up of material after Sampling Probability of mix up of material after Sampling Properties and Product failure & performed by untrained personnel. Propability of mix up of material after Sampling Properties and Product failure Propability of mix up of material after Sampling Properties and Product failure Properties and Product failure Properties are not provided for Storage of Garments Properties are not provided for Storage of Garments. Properties are not provided for storage of garments. Properties are not done in each container of material. Properties are not done in each container of material. Properties are not done in each container of material. Properties are not done in each container of material. Properties are not segregated Properties are not done in each container of material. Properties are not done in each container of material. Properties are not done in each container of material. Properties are not done in each container of material. Properties are not done in each container of material. Properties are not done in each container of material. Properties are not segregated Provision for controlled storage condition is available. Provision for controlled storage condition is available.	Probability of mix up of material after Sampling Probability of mix up of material after Sampling Properties of the failure and Product failure are not segregated Probability of mix up of material after Sampling Probability of mix up of material after Sampling Proper Status of Labeling is not done in each container of material. Proper Status of Labeling is not done in each container of material. Proper Status of Labeling is not done in each container of material. Proper Status of Labeling is not done in each container of material. Proper Status of Labeling is not done in each container of material. Proper Status of Labeling is not done in each container of material. Proper Status of Labeling is not done in each container of material. Proper Status of Labeling is not done in each container of material. Proper Status of Labeling is not done in each container of material. Proper Status of Labeling is not done in each container of material. Proper Status of Labeling is not done in each container of material. Proper Status of Labeling is not done in each container of material. Proper Status of Labeling is not done in each containers of materials properly identified by status label. Proper status label. Provision for controlled storage condition is available. Prov	Probability of use of Uning garments Product Failure & for Garments cleaning Garments cleaning are performed by untrained personnel. Probability of mix up of material after Sampling Propaging Product Failure & for Garments cleaning are performed by untrained personnel. Probability of mix up of material after Sampling Probability of mix in the container of material. Propability of mix up of material after Sampling Probability of use of University in the for Garments cleaning are performed by untrained person performing Sampling. Probability of use of University is not available. Proper Status of Labeling is not done in each container of material. Properly identified by status label. Properly identified by status label. Properly identified by status label. Proper storage of Sampled material and kept in Container with proper status label. Provision for controlled storage condition is available. Provision for controlled storage condition is available.	Probability of use of Universide garments Probability of use of Universide garments Probability of use of Universide garments Probability of mix up of material after Sampling Proper Status of Labeling is not done in each container of material. Proper Status of Labeling is not done in each container of material. Proper Status of Labeling is not done in each container of material. Proper Status of Labeling is not done in each container of material. Proper Status of Labeling is not done in each container of material. Proper Status of Labeling is not done in each container of material. Proper Status of Labeling is not done in each container of material. Proper Status of Labeling is not done in each container of material. Proper Status of Labeling is not done in each container of material. Proper Status of Labeling is not done in each container of material. Proper Status of Labeling is not done in each container of material. Proper Status of Labeling is not done in each container of material. Proper status label. Provision for controlled storage condition is available. Provision for controlled storage condition is available.	Probability of use of Uncleaned garments Probability of mix up of mix up of material after Sampling Propability of mix up of mix up of motor in a container of material after Sampling Propability of mix up of mix up of motor in container of material are not segregated Propability of mix up of motor in container of material after Sampling Propability of mix up of mix up of material after Sampling Propability of mix up of mix up of material after Sampling Propability of mix up of mix up of material after Sampling Propability of mix up of mix up of material after Sampling Propability of mix up of mix up of material after Sampling Propability of mix up of mix up of material after Sampling Propability of mix up	Probability of use of Uncleand garments Probability of mix up of material after Sampling Probability of mix up of material after Sampling Probability of use of Uncleanded garments cleaning Garments cleaning are performed by untrained personnel. Probability of mix up of material after Sampling Propability of use of Uncleanded garments Storage Cabinets are not provided for Storage of Garments. Proposability of mix up of material after Sampling Proposability of mix up of material after Sampling Proposability of mix up of material after Sampling Proposability of mix up of m	Probability of inix up of mixerial arier Sampling Probability of the Sampling Proposition of the performed by untrained personnel. Probability of mix up of mixerial arier Sampling Proposition of the person performing Sampling. Probability of use of Uncleaned garments Probability of mix up of mixerial arier Sampling Probability of mixerial cleaning are performed by untrained personnel. Probability of mixerial cleaning are performed by untrained personnel. Probability of mixerial cleaning are performed by untrained personnel. Probability of mixerial cleaning are performed by untrained personnel. Probability of mixerial cleaning are performed by untrained personnel. Probability of mixerial cleaning are performed by untrained personnel. Probability of mixerial cleaning are performed by untrained personnel. Probability of mixerial cleaning are performed by untrained personnel. Probability of mixerial cleaning are performed by untrained personnel. Probability of mixerial cleaning available. Probability of use of Untrained personnel. Probability of mixerial cleaning available. Probability of mixerial cleaning available. Provision for storage of ametrials and kept in Container with proper status label. Proper status label. Provision for controlled storage condition is available. Provision for controlled storage co	Probability of use of Uncleaned garments Probability of mix up of mix up of material after Sampling Probability of use of Uncleaned garments cleaning are performed by untrained personnel. Probability of mix up of mix up of material after Sampling Proper storage condition not followed. Proper storage condition is awailable. Proper storage condition not followed. Proper storage condition is awailable. Provision for controlled storage condition is awailable. Purchances Probability of use of Uncleaned Failure & Fai	Probability of use of Uncleaned garments Probability of mix up of material after Sampling Probability of use of Uncleaned garments cleaning are personnel. Probability of mix up of material after Sampling Probability of use of Uncleaned garments cleaning are personnel by untrained personnel. Probability of mix up of material after Sampling Probability of use of Uncleaned garments cleaning are personnel. Probability of mix up of mix up of material after Sampling Proper storage condition not followed. Proper storage condition not followed. Proper storage condition not followed. Provision for controlled storage condition is available. Punctuation of use of Uncleaning are personnel by untrained personnel. Probability of use of Uncleaned garments cleaning are personnel by untrained personnel. Probability of use of Uncleaned garments cleaning are personnel by untrained personnel. Probability of use of Uncleaned garments cleaning are personnel. Probability of use of Uncleaned garments cleaning are personnel. Probability of use of Uncleaned garments cleaning are personnel. Probability of use of Uncleaned garments cleaning are personnel. Probability of use of Uncleaned garments cleaning are personnel. Probability of use of Uncleaned garments and provided for storage of garments. Proper Status of Labeling is not done in each container of material. Proper storage of sampled material and kept in Container with proper status label. Provision for controlled storage condition is available. Provision for controlled storage condition is available. Puntained/Unqualified personnel is not allowed in					



QUALITY ASSURANCE DEPARTMENT

G	T. ,	D 4 41 3	D (() 1	D. C. I.C.		Defense	P	• 1	•41	C 4	D 11	D	C/		DDM						
S. No.	Item / Function	Potential Failure Mode	Potential Effect	Potential Cause/ Mechanism	Current Control	Reference				Current Ieasure	Recommended Actions	con	k afte trol	r	RPN (S*O*D)						
- 1,50			of Failure	of Failure	30333								(if any)								
			(Effect)							Risk											
							S	0	D	Priority Number		S	О	D							
										(S*O*D)											
	material			➤ Unclean Tools used for	➤ Material of Drum kept					()											
	Sampling			Sampling.	separate on different-																
					different pallets.																
				➤ RLAF not clean properly																	
				and Pressure Differential	➤ SOP for Sampling Tools																
				not in Limit.	cleaning is available.																
				➤ Weighing Balances are	Line clearance procedure																
				not clean.	followed before start of																
					Sampling procedure.																
		Personnel	Contamination	➤ Proper gowning	➤ Provision of Secondary	SOP	1	1	4	4	NA	NA	NA	NA	NA						
		Safety	of raw	procedure is not followed.	Change Room with																
		during	material and Effect on		secondary gowning																
		Sampling	Human		including Head gear, Body																
			Health		suit, and booties to avoid																
					contamination from persons																
					available.																
				➤ Safety devices are not	Safety devices are available																
				available.	i.e. PPE (personnel	Safety manual															
				a variable.	protective equipments),																
					Gloves, mask, goggles, etc																
					required safety devices are																
					provided. First aid facility is																
					provided in case of any miss																
					happening.																
				N T T 1 11 1/ · · · · · · · · · · · · · · · ·	➤ Untrained person is not																
				➤ Unskilled/untrained	allowed to work in sampling																
				person performing	area.																
				Sampling.	arca.																



QUALITY ASSURANCE DEPARTMENT

S. No.	Item / Function	Potential Failure Mode	of Failure	Potential Cause/ Mechanism of Failure	Control control Measure Actions (if any)				control Measure Actions control (if any) measure		trol	r	RPN (S*O*D)		
			(Effect)				S	o	D	Risk Priority Number (S*O*D)		S	o	D	
	Raw material Sampling			Activity is performed by without supervision of senior person.	 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	 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 	 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



QUALITY ASSURANCE DEPARTMENT

C	T4 - /	D-4 41 1	D-4 (* 1	D-44-1-C	C	Reference	- T-	·1		C 1	D	D' '	64		DDM
S. No.	Item / Function	Potential Failure Mode	Potential Effect	Potential Cause/ Mechanism	Current Control	Keierence				Current	Recommended Actions	cont	k afte	r	RPN (S*O*D)
140.	Function	ranule Mode	of Failure	of Failure	Control			control Measure Actions control (if any) measur				(S·O·D)			
			(Effect)	or randic				Risk		(ii any)	inca	Surc			
			(211000)						_	Priority		a		_	
							S	O	D	Number		S	O	D	
										(S*O*D)					
				untrained personnel.	➤ All activity is performed by										
					trained personnel.										
				➤ Dedicated area is not											
				provided for Storage of	➤ Dedicated area is provided										
				Cleaned sampling tools.	for Storage of Cleaned										
					dispensing tools.										
				➤ Separate Washing Area is											
				not provided.	Separate Washing Area is										
					provided.										
				➤ Dedicated AHUs is not											
				provided for all the area.	Dedicated AHUs is provided										
					for all the store area.										
				➤ Procedure is not available	B 1 : :111 6										
				for AHU cleaning & filter	➤ Procedure is available for										
				cleaning	AHU cleaning & filter										
				➤ Gowning procedure is not	cleaning										
				available & not followed.	Cii										
				avanable & not followed.	Gowning procedure is available & followed.										
				➤ Unidirectional men	avanable & followed.										
				material movement / Flow	➤ Unidirectional Men Material										
				are not provided.	Movement / Flow are										
				are not provided.	provided.										
				➤ Pictorial for gowning	provided.										
				procedure are not	➤ Pictorial for gowning										
				displayed in respective	procedure are displayed in										
				area.	respective area.										
				aiva.	respective area.										
				➤ Procedure is not available	➤ Procedure is available for										
				for Line clearance of											
				sampling area.	Line clearance of sampling										
				samping area.											



QUALITY ASSURANCE DEPARTMENT

FAILURE MODE EFFECT ANALYSIS FOR SAMPLING (LIQUID INJECTION)

S. Io.	Item / Function	Potential Failure Mode	Potential Effect of Failure (Effect)	Potential Cause/ Mechanism of Failure	Current Control	Reference	Risk with Current control Measure		control Measure		Recommended Actions (if any)	cont	x afte trol sure		RPN (S*O*D)
			(Effect)				S	o	D	Priority Number (S*O*D)		S	O	D	
				 ➤ Procedure is not available for cleaning of AHU & equipment filter ➤ Two different products sampled at a time. 	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.

FORMAT No.: Page 5 of 7



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

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

FAILURE MODE EFFECT ANALYSIS FOR SAMPLING (LIQUID INJECTION)

Remarks (if any):		

Quality Risk Ma	nagement Team		Reviewed By	Approved By
Name	Department	Sign & Date	Head Operations Sign & Date	Head QA Sign & Date

FORMAT No.: Page 6 of 7



QUALITY ASSURANCE DEPARTMENT

FAILURE MODE EFFECT ANALYSIS FOR SAMPLING (LIQUID INJECTION)

QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

Name of Facility	/ Equipment / Utility / System / Activity / Procedure / Unit Operation:	Sampling (Liquid Injection)	
S. No.	Recommended Action	Responsible Person	Target Date of Completion
	greed actions completed, Not Completed. commendations Not completed, to be tracked through CAPA System)		
Verified By QA Sign & Date		Approved I Head QA Sign & Da	

FORMAT No.: