PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN

QRA No.:……..

Name of Equipment: Facility Processes

Date Of Quality Risk Assessment:

S. No.	Item/Function	Potential Failure Mode (Failure mode)	Potential Effect of Failure	Potential cause/Mechanism of Effect of Failure	Current control	Reference	Severity	Occurrence	Detection	Risk Priority Number	Recommended Actions (If any)	Post Risk			
												Severity	Occurrence	Detection	Risk Priority Number
1.	RM Dispensing	1) Inaccuracy of weighing balance during dispensing	1) It can be cause of variation in weight of RM during weighing and also cause variation in assay of product.	1) Due to out of calibration of weighing balance	1) Calibration of weighing balance is done on monthly basis and daily verification of weighing balance is also done to check its accuracy.	SOP	4	1	1	4					
		2) RM is not of appropeate quality	2) It can be cause of low assay and low stability of finish product.	2. A) RM testing not done during receiving of RM. 2. B) Receiving of Raw material from an unapproved vender.	2. A) there is a provision for sampling & testing of raw materials and All raw materials Have been sampled and tested as per the written procedures and only after that QC approved RM is used for further processes. 2. B) Before procurement of materials all venders has been qualified & approved as per our written procedure for vender management.	SOP	4	1	1	4					
		3) Unapproved material used for dispensing process	3) It can be very harmful for whole batch and could be cause of low assay of finish product.	3) Due to not proper testing by quality control department.	3) There is a proper provision for sampling, testing and labeling (approved or rejected) of raw material and before dispensing raw material verified by quality assurance department for its approved status.	SOP	4	1	1	4					

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN

Name of Equipment: Facility Processes

Date Of Quality Risk Assessment:

S. No.	Item/Function	Potential Failure Mode (Failure mode)	Potential Effect of Failure	Potential cause/Mechanism of Effect of Failure	Current control	Reference	Severity	Occurrence	Detection	Risk Priority Number	Recommended Actions (If any)	Post Risk			
												Severity	Occurrence	Detection	Risk Priority Number
		4) Gowning procedure not followed for dispensing	4) There might be a chance of contamination of Raw Material.	4) If untrained person will enter in the dispensing area.	4) Only trained persons are authorized to enter in dispensing area followed by the authorized person list.	SOP	2	1	1	2					
		5) Temperature and RH out of limit during dispensing	5) It can be effects the property of Raw material and due to more RH, it can create moisture in Raw material.	5) Failure of HVAC system or unqualified AHU'S are in use.	5) Qualified HVAC System is used in our facility and we also have a provision of BMS system for controlling and monitoring of Temp. & RH.	BMS Qualificati	4	2	1	8					
		6) No proper cleaning during dispensing process	6) There might be a chance of contamination of Raw Material.	6) If untrained person will enter in the dispensing area.	6) Written procedures are available for cleaning processes and quality assurance person daily verify the cleaning of dispensing room.	SOP	2	2	1	4					
		7) Malfunctioning of Dispensing Booth	7) Due to that cross contamination of raw material will occurred	7) No proper maintenance is there for dispensing booth and Unqualified dispensing booth used for dispensing.	7) Qualified Dispensing booth is using for dispensing purposes and there is a provision for daily monitoring of differential pressure of dispensing booth through its magnehelic gauges. There is also a written procedure for preventive maintenance of all equipment including with dispensing booth.	RLAF Qualification	3	2	1	6					

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN

Name of Equipment: Facility Processes

Date Of Quality Risk Assessment:

S. No.	Item/Function	Potential Failure Mode (Failure mode)	Potential Effect of Failure	Potential cause/Mechanism of Effect of Failure	Current control	Reference	Severity	Occurrence	Detection	Risk Priority Number	Recommended Actions (If any)	Post Risk			
												Severity	Occurrence	Detection	Risk Priority Number
2.	Transfer the dispensed material from store to Manufacturing	1. Material spillage 2. Material misplace during transfer.	Directly impacted to the product manufacturing & product quality.	1) Not Proper handling during transferring of materials.	1) After dispensing all materials are kept in dispensing bags and close with cable tie with a specific numbering on each material. 2) We have a provision to transfer all the dispensed materials in a closed SS Container.	SOP	4	1	1	4					
3.	Manufacturing Process	1) Weight verification not done after dispensing process.	Could not verify if there is a loss of dispensed raw material during transfer from dispensing room to manufacturing room.	Due to no provision of verification in manufacturing room.	All dispensed materials are kept in separate dispensing poly bags and closed with cable tie and after dispensing all dispensed materials are kept in a SS container with lock n key.		2	1	1	2					
		2) Failure in load cell of manufacturing tank during batch mixing.	1) Due to that the actual process of manufacturing with respect to actual weight of WFI will not be accurately matched and it can be affected the batch manufacturing process.	1) Sensitivity of load cell indicator & controller may failed	1) Three load cell has been installed in there, and verification of load cell shall be check before start of batch manufacturing of mfg. tank.		4	1	1	4					

Where: S=Severity; O=Occurrence Probability; D=Detection; Risk category 1-25 RPN is Low risk, 26-50 RPN is Medium Risk, 51-125 RPN is High Risk.

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN

Remarks (if any): The entire above failure mode and their Severity, Occurrence, Detection rating done and found RPN No. in between 4 to 8 and Post RPN No. in between 3 to 8. Hence Risk is low detected, it's acceptable.

Quality Risk Management Team			Reviewed By Concerned Department Head Sign & Date	Approved By Head QA Sign & Date
Name	Department	Sign & Date		
	QA			
	PRODUCTION			
	STORE.			

QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

Name of Equipment: Air Handling Unit System.

S.No.	Recommended Action	Responsible Person	Target Date of Completion
	NA	NA	NA

Verification of Action Plan:
NA.

Remarks (if any): NA

Verified By
QA
Sign & Date

Approved By
Head QA
Sign & Date