PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN FOR FACILITY PROCESSES

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	S	O	D	Risk Priority Number	Recommended Actions (If any)	Post Risk			
											S	O	D	RPN SxOxD
1.	RM Dispensing	Inaccuracy of weighing balance during dispensing	It can be cause of variation in weight of RM during weighing and also cause variation in assay of product.	Due to out of calibration of weighing balance	Calibration of weighing balance is done on monthly basis and daily verification of weighing balance is also done to check its accuracy.	4	1	1	4	NA	NA	N A	N A	NA
		RM is not of appropeate quality	It can be cause of low assay and low stability of finish product.	A) RM testing not done during receiving of RM. B) Receiving of Raw material from an unapproved vender.	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. B) Before procurement of materials all venders has been qualified & approved as per our written procedure for vender management.	4	1	1	4	NA	NA	N A	N A	NA
		Unapproved material used for dispensing process	It can be very harmful for whole batch and could be cause of low assay of finish product.	Due to not proper testing by quality control department.	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.	4	1	1	4	NA	NA	N A	N A	NA

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											S	O	D	RPN SxOxD
		Gowning procedure not followed for dispensing	There might be a chance of contamination of Raw Material.	If untrained person will enter in the dispensing area.	Only trained persons are authorized to enter in dispensing area followed by the authorized person list.	4	1	1	4	NA	NA	NA	NA	NA
		Temperature and RH out of limit during dispensing	It can be effects the property of Raw material and due to more RH, it can create moisture in Raw material.	Failure of HVAC system or unqualified AHU'S are in use.	Qualified HVAC System is used in our facility and we also have a provision of BMS system for controlling and monitoring of Temp. & RH.	4	1	1	4	NA	NA	NA	NA	NA
		No proper cleaning during dispensing process	There might be a chance of contamination of Raw Material.		Written procedures are available for cleaning processes and quality assurance person daily verify the cleaning of dispensing room.	4	1	1	4	NA	NA	NA	NA	NA
		Malfunctioning of Dispensing Booth	Due to that cross contamination of raw material will occurred	No proper maintenance is there for dispensing booth and Unqualified dispensing booth used for dispensing.	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.	4	1	1	4	NA	NA	NA	NA	NA

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											S	O	D	RPN SxOxD
2.	Transfer the dispensed material from store to Manufacturing	Material spillage Material misplace during transfer.	Directly impacted to the product manufacturing & product quality.	Not Proper handling during transferring of materials.	After dispensing all materials are kept in dispensing bags and close with cable tie with a specific numbering on each material. We have a provision to transfer all the dispensed materials in a closed SS Container.	4	1	1	4	NA	NA	NA	NA	NA
3.	Manufacturing Process	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.	4	1	1	4	NA	NA	NA	NA	NA
		Failure in temperature indicator controller & Temperature sensor of manufacturing tank during batch mixing.	Due to that the actual process of manufacturing with respect to actual temperature of WFI will not be accurately matched and it can be affected the batch manufacturing process.	Sensitivity of temperature indicator controller & Temperature sensors may failed	Calibration and performance of temperature indicator controller & temp. Sensors shall be check during operational qualification of mfg. tank.	4	1	1	4	NA	NA	NA	NA	NA

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											S	O	D	RPN SxOxD
4.		Mixing time & Volume Variation during manufacturing of bulk.	Variation in desired assay result.	Due to invisible marking on dipstick and/or Untrained operator perform batch manufacturing.	Batch Manufacturing process is done in presence of QA and Production supervision to ensure correctness of all parameters according to BMR. Periodic calibration of dipstick is done to ensure exact marking.	4	1	1	4	NA	NA	NA	NA	NA
5.	Filtration Process	Availability of non-sterile solution for aseptic filling.	There might be a chance of Product Contamination.	Integrity failure of 0.22µ sterile filter and/or use of unsterilized articles during filtration process.	Pre and post filter integrity has been done before and after filtration process to ensure integrity of 0.22µ sterile filter. On line CIP & SIP System is in place for providing a better process result so that all equipment's should be sterile for filtration process.	4	1	1	4	NA	NA	NA	NA	NA

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN FOR FACILITY PROCESSES

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.

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			
	ENGG.			

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