PHARMA DEVILS

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN

QRA No.:

Name of Facility/Equipment/Utility/System/Activity/Procedure **Unit Operation**: Media Fill Activity	**Date Of Quality Risk Assessment:**

S. No.	Item/ Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure (Effect)	Potential Cause/ Mechanism of Failure	Current Control	Reference	S	O	D	Risk Priority Number (S*O*D)	Recommend-ended Actions (if any)	Post Risk			
												S	O	D	RPN S*O
Dispensing															
1.	Dispensing stage	➢ Fail to dispense the required quantity.	➢ Inadequate result due to improper quantity dispensing.	➢ Due to selection of wrong capacity of weighing balance.	➢ Selection of weighing balance shall be done on the basis of weighing balance capacity and dispense quantity of material. ➢ SOP for weighing Balance calibration shall be in place.	Operation, Cleaning, Calibration and Verification of Weighing Balances	4	1	1	4 Low category & Risk Accepted	Adequate procedure no recommendation required	NA	NA	NA	NA
		➢ Dispense material get contaminate	➢ Contamination of the area leading to contamination of material.	➢ Due to improper environmental condition.	➢ Environmental condition shall be monitored before and after start of activity in respective BMR.										
				➢ Due to unavailability of dispensing tools.	➢ Uses and cleaning of dispensing tool SOP is in place.										
				➢ Due to lack of procedure for dispensing	➢ Dispensing of RM,PPM and API SOPs are in place.										
				➢ Material dispensed by untrained personnel.	➢ Training has been imparts to all concerned personnel's.										
				➢ Not cross checked during dispensing.	➢ During Dispensing activity done by and checked by provision is available in BMR and verification done by IPQA.										

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												S	O	D	RPN S*O
2.	Component preparation	➢ Improper component preparation and sterilization procedure.	➢ Improper cleaning and sterilization of component leads to microbial growth. ➢ Due to microbial growth leads to media failure.	➢ Unqualified equipment use for sterilization. ➢ Inadequate component cleaning procedure and sterilization procedure. ➢ Lack of steam or utility cut off during sterilization phase. ➢ Articles cleaning and sterilization by untrained person. ➢ Load pattern may not follow. ➢ Selection of wrong recipe. ➢ Sensor malfunctioning ➢ Due sterilized material hold time cross.	➢ Qualification of Autoclave i has been completed. ➢ Component cleaning and sterilization SOP is in place. ➢ If the steam lack occurs during sterilization phase, alarm will generate and same shall be acknowledged by operator and cycle will be considered as abort. ➢ Training has been imparted to all concerned persons. ➢ Validated load patterns should be refers before start of activity as per respective SOP. ➢ Validated recipe and parameter has been incorporated in SOP. ➢ Defined frequency in place for schedule calibration, Preventive maintenance and validation status.	Cleaning and Sanitation of Aseptic/Manufacturing/Washing and Sterilization/Vial Sealing Area	4	2	1	8 Low category & Risk Accepted		NA	NA	NA	NA

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												S	O	D	RPN S*O
3.	Manufacturing Process	➢ Sterilization not done of manufacturing tank.	➢ Chemical & Microbial contamination increases in manufacturing vessel.	➢ SOP for Cleaning & sanitization not followed. ➢ Working personnel lack of adequate knowledge.	➢ Written procedures are available for cleaning & sanitization processes and quality assurance person verify the sterilization process of manufacturing tank. ➢ Online SIP (Sterilization in Place) system is available for sterilization.	SOP	4	1	1	4 Low category & Risk Accepted	Adequate procedure no recommendation required.	NA	NA	NA	NA
		➢ WFI failed during testing.	➢ Batch Directly Impacted, Chance to increases microbial level in final product.	➢ WFI not meet its predetermined specification. ➢ Sampling & testing of WFI not done on correct manner.	➢ Before manufacturing WFI sample shall be send for pH, Conductivity & BET test & Procedure Incorporated in BMR.	SOP	4	3	1	12 Low category & Risk Accepted	Adequate procedure no recommendation required.	NA	NA	NA	NA
		➢ 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.	SOP	3	3	1	9 Low category & Risk Accepted	Adequate procedure no recommendation required.	NA	NA	NA	NA

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												S	O	D	RPN S*O
	Manufacturing Process.	➢ 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.	SOP	3	3	1	9 Low category & Risk Accepted	Adequate procedure no recommendation required.	NA	NA	NA	NA
		➢ 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.	SOP	3	3	1	9 Low category & Risk Accepted	Adequate procedure no recommendation required.	NA	NA	NA	NA

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		➢ Heating or cooling the solution	➢ Increase of impurities and can be a chance dissolution difficulties.	➢ There can be a mechanical problem (in heater or chiller)	➢ Temperature limits for applicable steps are written in the batch manufacturing records and are double check by production and quality assurance person. ➢ Preventive maintenance is done as per schedule.	SOP	3	2	1	6 Low category & Risk Accepted	Adequate procedure no recommendation required.	NA	NA	NA	NA

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												S	O	D	RPN S*O
	Manufacturing Process.	➢ Improper manufacturing of Media	➢ Due to improper manufacturing procedure bioburden may increase more than specification. ➢ Failure during compounding may lead to loss of time and resources. ➢ Unexpected outcome like yield and concentration of media may lead to media failure.	➢ Compounding procedure not available. ➢ Due to lack of calibration ,preventive maintenance, operational and cleaning procedures. ➢ Due to lack of qualification procedure. ➢ Unsterlized and unclean equipment may use. ➢ Inadequate cleaning or equipment's difficult to clean. ➢ Due to compounding activity handle by untrained person. ➢ Due to lack of clean equipment hold time may cross. ➢ Micro growth due to utility supply such as WFI, Compressed air.	➢ Vessel calibration, preventive maintenance, operational and cleaning procedure are in place. ➢ Qualification of vessels system is completed. ➢ In line clearance of compounding activity ensure the sterilization vessels shall be mention in BMR. ➢ Vessels CIP, SIP procedure are qualified and SOP is in place. ➢ Training has been completed for all concerned persons. ➢ Water system and compressed air are qualified.	Load Cell Verification and Calibration of Manufacturing Vessels	4	1	1	4 Low category & Risk Accepted	Adequate procedure no recommendation required.	NA	NA	NA	NA

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	Mixing tank to Holding tank Transfer line.	➢ Cleaning not done of mixing tank to holding tank transfer line.	➢ Microbial contamination increases in transfer line. ➢ There might be a chance of contamination of product.	➢ Online monitoring for cleaning of product line not available ➢ Cleaning process of transfer line interrupted. ➢ Cleaning of transfer line not followed as per SOP. ➢ No proper procedure for cleaning of transfer line.	➢ Product line cleaned with manufacturing tank and online conductivity sensor has been installed at the end of Drain line and recipe has been set when conductivity not achieve then cleaning continue still get conductivity 1.3 µ siemen. ➢ Print facility available for reviewing of cleaning Process	SOP	4	3	1	12 Low category & Risk Accepted	Adequate procedure no recommendation required.	NA	NA	NA	NA
		➢ Sterilization not done of mixing tank to holding tank transfer line.	➢ Directly impacted to Product Sterility & Quality. ➢ Product gets contaminated after filtration.	➢ Due to assembling of Product line after sterilization, intact line and online sterilization facility not available.	➢ Product line Sterilized with manufacturing tank and online temperature sensor has been installed at the end of product line and recipe has been set sterilization hold cycle not started when temperature not achieve at that end point of product line. ➢ Print facility available for reviewing of sterilization Process.	SOP	4	2	1	8 Low category & Risk Accepted	Adequate procedure no recommendation required.	NA	NA	NA	NA

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10.	During Filter Integrity testing	➢ Improper filter integrity procedure	➢ Inadequate result of filter integrity may directly impact on sterility of product. ➢ Due to improper filter integrity media failure.	➢ Equipment may not qualify. ➢ Unavailability of SOP. ➢ Filter integrity activity handled by untrained person. ➢ Selection of wrong parameters and recipe ➢ No cross check provision for filter integrity report.	➢ Qualification of filter integrity machine has been completed. ➢ Operational SOP is in place ➢ Training has been imparted to all concerned persons. ➢ Validated recipe and parameter has been incorporated in SOP. ➢ Filter integrity report(Pre and Post) shall be checked by production person and verified by QA person.	Operation of Integrity Tester	3	1	1	3 Low category & Risk Accepted	Adequate procedure no recommendation required.	NA	NA	NA	NA

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												S	O	D	RPN S*O
11.	Bulk hold	➢ Fails to Bulk hold	➢ During bulk solution hold period bioburden may increase more than the specification. ➢ Failure during bulk hold leads to loss of time and resources	➢ Due to lack of qualification of vessel system. ➢ Due to lack of aseptic connection. ➢ Due to lack of positive pressure. ➢ Due to failure of filter integrity of vent filters. ➢ Due to lack of provision to monitor the pressure in vessel. ➢ Due to activity handled by untrained person.	➢ Qualification of vessel system has been completed. ➢ The vessel is close system and operated through control HMI. ➢ The vessel kept under positive pressure during bulk hold which does not allow the infilteration of microbial contaminants. ➢ The procedure is in place for pre and post filter integrity for vent failure. ➢ Magnehelic guage is there for monitoring the pressure. ➢ Training pressure is in place for operation of the vessel.	Load Cell Verification and Calibration of Manufacturing Vessels	4	1	1	4	Adequate procedure no recommendation required	NA	NA	NA	NA

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												S	O	D	RPN S*O
12.	Filtration activity	➢ Improper filtration	➢ Filtered is not sterile leads to microbial growth. ➢ Improper filtration leads to media fill failure.	➢ Due to lack of procedure to sterilize the filter. ➢ Due to lack of procedure to check the integrity of filter. ➢ Due to improper training to concerned persons. ➢ Due to lack of filteration procedures. ➢ Due to lack of filter validation. ➢ Due to insufficient utility supply.	➢ SOP is in place for online SIP of filtered. ➢ Filter integrity procedure is available. ➢ Training procedure is in place. ➢ SOP in –place for Filtration . ➢ Sufficient utility supply is in place.	SIP for Mixing Vessel/ MMV/ Holding Vessel/Buffer Vessel	4	2	2	16	Filter validation shall be established.	4	1	1	4

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13.	Vial washing	➢ Improper washing of vial	➢ Improper vial washing procedure leads to contamination ➢ Due improper cleaning particulate matter may presence in vials and leads to media fill failure.	➢ Lack of qualified equipment. ➢ Lack of operational procedure. ➢ Due to activity handled by untrained person. ➢ Due to lack of cleaning operation and preventive maintenance procedure. ➢ Due to improper utility supply.	➢ Qualification has been completed for vial washing machine. ➢ Operational SOP is in place. ➢ Training has been imparted to concerned persons. ➢ Cleaning, operational and preventive maintenance procedures is in place. ➢ Sufficient utility supply is in place.	Operation and Cleaning Vertical Rotary of Washing Machine	4	1	1	4	Adequate procedure no recommendation required	NA	NA	NA	NA

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14.	Tunnel operation	➢ Improper depyrogenation to vial.	➢ Improper depyrogenation leads BET failure. ➢ Failure in tunnel leads to loss of time and resources.	➢ Unqualified equipment may use. ➢ Lack of operational procedure. ➢ Untrained person may operate machine ➢ Inadequate cleaning procedure. ➢ Tunnel temperature and DP fluctuation during batch activity ➢ Selection of wrong parameters and recipe.	➢ Qualification has been completed for tunnel. ➢ Operational SOP is in place. ➢ Training has been imparted to concerned persons. ➢ Cleaning SOP is in place. ➢ Tunnel conveyer belt will stop automatically if sensor temperature goes out of set point and defined frequency is in place for schedule calibration, temperature sensor, Preventive maintenance and validation status of tunnel sterilizer. ➢ Validated recipe and parameter is in place.	Operation of Cleaning of Sterilizing & Depyrogenation Tunnel	4	2	1	8	Adequate procedure no recommendation required	NA	NA	NA	NA

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												S	O	D	RPN S*O
15.	Filling operation	➢ Improper filling and stoppering	➢ Improper filling may result in volume variation. ➢ Lack of aseptic behavioural during filling and stoppering activity may leads to contamination and media fill failure.	➢ Lack of qualification procedure. ➢ Lack of cleaning and operational procedure. ➢ Unsterile parts or article may use I filling operation. ➢ Lack of environmental condition for filling. ➢ Improper handling of aseptic intervention may lead to product contamination. ➢ Operation handled by untrained and unqualified person. ➢ Due aseptic interventions ➢ during filling duration.	➢ Qualification of filling and stoppering machine has been completed. ➢ SOP for filling machine cleaning and operation is in place. ➢ Sterilization procedure for machine parts loads is in place. ➢ Filling shall be carried out under class A condition(Unidirectional air flow area) ➢ Aseptic intervention shall be performed as per media fill protocol and BMR. ➢ Operational training has been done for all concerned persons for aseptic. ➢ Aseptic interventions has been established in media fill process simulation study. ➢ Filling duration has been validated in media fill .	Operation and Cleaning of Automatic High Speed Injectable Powder Filling and Stoppering Machine	4	2	1	8	Adequate procedure no recommendation required	NA	NA	NA	NA

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16.	Capping operation	➢ Improper capping operation	➢ Chance of contamination during capping activity due to crimping is not provide leak proof sealing to the vials. ➢ Failure in capping activity leads to loss of time and resources.	➢ Unqualified equipment may use. ➢ Operational and cleaning procedure may not available. ➢ Untrained person may operate machine. ➢ Lack of leak test procedure for sealed container.	➢ Qualification for capping machine has been completed. ➢ Operational and cleaning SOP is in place. ➢ Training has imparted to concerned persons. ➢ SOP is in place for leak test for sealed container and closers.	Operation & Cleaning of Filling, Dropper Fixing & Screw Capping Machine	3	2	1	6	Adequate procedure no recommendation required	NA	NA	NA	NA
17.	Incubation process	➢ Improper incubation	➢ Improper incubation may leads to false result. ➢ Failure during incubation process of media fills vials leads to loss of time and resources.	➢ Incubators may not qualify. ➢ Due to power failure. ➢ Due to data back up not available. ➢ Lack of calibration, preventive maintenance and validation procedure.	➢ Qualification for incubators has been completed. ➢ UPS supply is available. ➢ Software is available for data back-up ➢ Calibration, preventive maintenance and validation procedure is in place.	Operation, Calibration &Maintenance of BOD Incubators & Bacteriological Incubators	4	2	1	8	Adequate procedure no recommendation required	NA	NA	NA	NA

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18.	Cleaning agent and Disinfectant	➢ Improper disinfectant preparation, area cleaning and sanitization process.	➢ Leads to area and product contamination. ➢ Failure in area cleaning and disinfectant preparation activity leads to loss of time and resources.	➢ Disinfectant not qualified ➢ SOP not available for disinfectant preparation. ➢ Lack of area cleaning and disinfectant preparation procedure. ➢ Area cleaning and disinfectant preparation done by untrained person.	➢ SOP is in place for disinfectant preparation. ➢ SOP is in place for area cleaning and disinfectant and preparation. ➢ Training has been imparted to concerned persons.	Preparation, Filtration, Usage and Destruction of Disinfectant Solution	4	2	2	16	Adequate procedure no recommendation required	NA	NA	NA	NA

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												S	O	D	RPN S*O
19.	Entry Exit and personal monitoring	➢ Failure in following personnel gowning and entry exit area process for critical area.	➢ Improper gowning procedure may leads to contamination in area and product. ➢ Failure in area cleaning and disinfectant preparation activity leads to loss of time and resources.	➢ Unavailability of gowning procedure and gowning qualification program. ➢ Lack of garment sterilization procedure. ➢ Unavailability of dedicated storage area. ➢ Garment hold period may cross. ➢ Lack of controls restricted entry in critical area. ➢ Persons not maintaining personnel hygiene.	➢ SOP for gowning procedure and gowning qualification are in place. ➢ Garments shall be sterilized as per validated load pattern. ➢ Garments should be store under class A condition(LAF cabinet) ➢ Personnel restricted entry controlled by biometric assess system. ➢ Garment hold time study has been validate. ➢ SOP is in place for personnel hygiene and aseptic behavioral practices in critical area. ➢ Personnel hygiene and aseptic behavioral practices in critical area. Training has been imparted to concerned persons before entering in critical area.	Personnel Monitoring by Contact Plate and Finger Dab	4	2	1	8	Adequate procedure no recommendation required	NA	NA	NA	NA

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.

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Name of Facility/Equipment/Utility/System/Activity/Procedure/Unit Operation : Media Fill Activity		Date:	
S. No.	**Recommended Action**	**Responsible Person**	**Target Date of Completion**
1.	NA	NA	NA
2.	NA	NA	NA

CAPA:
If required, mention CAPA No.:

Quality Risk Management Team			**Reviewed By Head Production 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 : Media Fill Activity

Verification of Action Plan: NA

Remarks (if any): The entire above failure mode and their Severity, Occurrence, Detection rating done and RPN No. is found between 1-25. Hence Risk is detected as low which is acceptable.

Verified By
QA
Sign & Date

Approved By
Head QA
Sign & Date