PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN

QRA No.:

Name of Facility/Equipment/Utility/System/Activity/Procedure **Unit Operation**: **Description:** The objective of the risk assessment is to evaluate the risk associated during the Process Validation Batch of Lidocaine Injection 2%w/v 20 ml Injection	**Date of Quality Risk Assessment:**

Sr. 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
1.	Dispensing stage- Before start of Dispensing	➢ Unapproved material gets dispense ➢ Failed material get dispense	➢ Unapproved dispense material leads to product contamination. ➢ Fails to achieve the safety, efficacy and quality of product.	➢ Lack of Qualified source of API and Excipients. ➢ Lack of testing specification. ➢ Lack of vendor management procedure	➢ Qualification procedure is in place and also line clearance check point is available in BMR to ensure approved & release materials are available for dispensing. ➢ Testing specifications are in place. ➢ Vendor management procedure is in place.	Vendor Management & SOP SOP	4	1	1	4	Adequate procedure no recommendation required	NA	NA	NA	NA

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2.	At the time of Dispensing	➢ Fails to dispense the required quantity. ➢ Dispense material get contaminate.	➢ Inadequate result due to improper quantity dispensing and improper testing outcomes (OOS). ➢ Contamination of the area leads to product failure	➢ Due to selection of wrong capacity weighing balance. ➢ Due to lack of operational and calibration procedure of weighing balance. ➢ Due to improper environmental conditions. ➢ Due to lack of the operation and cleaning procedure for dispensing tools. ➢ Due to lack of procedure for dispensing ➢ Material dispensed by untrained personnel. ➢ No cross check during dispensing ➢ Unapproved/rejected material Dispensed.	➢ Selection of weighing balance is depending on balance capacity and quantity of material. ➢ SOP is in place for operation and calibration procedure of weighing balances. ➢ Environmental condition check point is in place in line clearance checklist. ➢ Uses and cleaning of dispensing tool SOP is in place. ➢ Dispensing of API, excipients and PM SOP's are in place. ➢ Training has been imparted to concerned personnel's. ➢ In dispensing activity done by and checked by provision is available in BMR and verification done by before compounding. ➢ Check point is in place in BMR to check material is approved/released.	Operation & Verification of Balances	3	2	1	6	Adequate procedure no recommendation required	NA	NA	NA	NA

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												S	O	D	RPN S*O
3.	Component preparation	➢ Failure of Component preparation and sterilization.	➢ Improper cleaning and sterilization of component leads to contamination in product.	➢ Due to lack of unqualified sterilizer. ➢ Lack of component cleaning and component sterilization procedure. ➢ Steam lack 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 to sterilization, equipment hold time cross	➢ Qualification of sterilizer has been completed. ➢ Component cleaning and sterilization SOP is in place. ➢ If the steam lack occurs during sterilization phase, alarm has been generate and same acknowledged by operator and cycle considered as abort. ➢ Training has been imparted to all concerned persons. ➢ Validated load patterns have been refers before start of activity as per respective SOP. ➢ Validated recipe and parameter has been set in autoclave PLC and controlled through password. ➢ Defined frequency in place for schedule calibration, Preventive maintenance and validation status. ➢ Sterilized hold time has been established and actual equipment hold time is track in BMR.	Operation and Cleaning of Autoclave Cum Bung Processer	3	2	1	6	Adequate procedure no recommendation required	NA	NA	NA	NA

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												S	O	D	RPN S*O
4.	During Filter Integrity testing	➢ Failure in filter integrity	➢ Improper filter integrity gets direct impact on sterility of product.	➢ Unqualified equipment used. ➢ Lack of cleaning and operational SOP. ➢ Filter integrity activity performed by untrained person. ➢ No cross checks provision for filter integrity test report.	➢ Qualification of filter integrity machine has been completed. ➢ Cleaning and Operational SOP is in place ➢ Training has been imparted to all concerned persons and user ID given after completion of training. ➢ Filter integrity test report (Pre and Post) has been checked by production person and verified by QA person.	Operation of Integrity Tester	4	3	1	12	Adequate procedure no recommendation required	NA	NA	NA	NA
5.	Filtration activity	➢ Failure in filtration of bulk solution	➢ Filtrate is not sterile leads to microbial growth. ➢ Improper filtration leads to contamination in product.	➢ Lack of procedure for sterilization of filter. ➢ Lack of procedure to check the filter integrity. ➢ Due to improper training to concerned persons. ➢ Lack of filtration procedures.	➢ SOP is in place for SIP of vessel system along with product transfer line. ➢ Filter integrity procedure is in place check points is available. ➢ Training procedures is in place. ➢ Filtration procedure is available in BMR.	SIP for Mixing Vessel/ MMV/ Holding Vessel/Buffer Vessel	4	2	1	8	Adequate procedure no recommendation required	NA	NA	NA	NA

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6.	During compounding	➢ Failure in Batch manufacturing	➢ Due to improper manufacturing procedure leads to Bioburden may increase more than specification. ➢ Unexpected outcome like yield and concentration of product leads to product failure.	➢ Compounding procedure not available. ➢ Due to lack of calibration, preventive maintenance, operational and cleaning procedures. ➢ Qualification of vessel system not available. ➢ Unsterilized and unclean equipment may use. ➢ Inadequate cleaning or equipment's difficult to clean. ➢ Compounding activity handle by untrained person. ➢ Due to lack of clean equipment hold time may cross.	➢ Detail, compounding procedure is in place in BMR. ➢ Vessel calibration, preventive maintenance, operational and cleaning procedure are in place. ➢ Qualification of vessels system is completed. ➢ In line clearance of compounding activity ensures the sterilization vessels has been mention in BMR. ➢ Vessels CIP, SIP procedure are qualified and SOP is in place. ➢ Training has been completed for all concerned persons. ➢ SIP hold time has been established. ➢ Water system, compressed air and Nitrogen are qualified.	Load Cell Verification of all vessels	4	2	1	8	Adequate procedure no recommendation required	NA	NA	NA	NA

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												S	O	D	RPN S*O
7.	Bulk Hold	➢ Failure in Bulk Hold	➢ During bulk solution hold period Bioburden may increase more than the specification.	➢ Lack of qualification of vessel system. ➢ Lack of aseptic connection. ➢ Lack of positive pressure. ➢ Due to failure of filter integrity of vent filters. ➢ Lack of provision to monitor the pressure in vessel. ➢ Due to activity handle by untrained person. ➢ Lack of established bulk hold time.	➢ Qualification of the vessel system has been completed. ➢ Aseptic connection for filtration is defined in BMR. ➢ The vessel is closed system and operated through control HMI. The vessel kept under positive pressure during bulk hold which does not allow the infiltration of microbial contaminants. ➢ Magnehelic gauge is there for monitoring the pressure ➢ Training procedure is in place for operation of the vessel.	Handling of Filters	4	3	1	12	Adequate procedure no recommendation required	NA	NA	NA	NA
8.	Vial Washing	➢ Failure in washing	➢ Improper washing procedure leads to contamination ➢ Due to improper cleaning particulate matter may presence in vials and leads to failure in visual inspection.	➢ 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 are in place. ➢ SOP is in place for parameter of utility supply.	Operation and Cleaning of Vial Washing Machine	5	1	1	5	Adequate procedure no recommendation required	NA	NA	NA	NA

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												S	O	D	RPN S*O
9.	Tunnel operation	➢ Failure in vials depyrogenation	➢ Improper depyrogenation leads BET and Sterility Failure. ➢ Failure in tunnel leads to loss of time and resources.	➢ Unqualified equipment may use. ➢ Lack of cleaning and operational procedure. ➢ Untrained person may operate machine ➢ Tunnel temperature and DP fluctuation during batch activity ➢ Selection of wrong parameters and recipe ➢ Sensor malfunctioning.	➢ 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 stop automatically if sensor temperature goes out of set point.. ➢ 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	5	2	1	10	Adequate procedure no recommendation required	NA	NA	NA	NA

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10.	Filling operation	➢ Failure in filling and stoppering	➢ Improper filling may result in volume variation. ➢ Improper filling and stoppering activity may leads to contamination.	➢ 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 ➢ Due 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. ➢ Filling duration is mentioned in BMR and same was simulated in media fill.	Operation and Cleaning of Vial filling machine	5	1	2	10	Adequate procedure no recommendation required	NA	NA	NA	NA

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11.	Visual Inspection	➢ Failure in visual inspection	➢ Improper visual inspection of vials leads to direct impact on product quality and patient safety. ➢ Improper visual inspection to vials gets market complaints to the organization.	➢ Lack of qualification procedure for visual inspector. ➢ Lack of SOP for visual inspection procedure. ➢ Visual inspection activity done by unqualified person. ➢ Lack of cross check procedure for inspected vial. ➢ Visual inspection hood not qualified. ➢ Lack of required lux level.	➢ Visual inspector qualification procedure is in place. ➢ SOP is in place for Automatic optical inspection activity. ➢ Qualification has been completed for concerned persons. ➢ In process checks is in place for visual inspection activity and AQL is in place.	Operation Cleaning of Automatic Visual Inspection Machine	3	2	1	6	Adequate procedure no recommendation required	NA	NA	NA	NA
12.	Storage condition in FG	➢ Improper storage space and conditions in finished goods store.	➢ Chance of product mix-up due to lack of dedicated space. ➢ Chance of product degradation due to irrespective storage condition.	➢ Lack of SOP ➢ Lack of dedicated storage space ➢ Due to environmental condition not maintain.	➢ SOP for handling of finished goods is in place. ➢ Dedicated storage space is available. ➢ Environmental condition is monitoring through BMS.	Handling of Finished Goods	2	2	1	4	Adequate procedure no recommendation required	NA	NA	NA	NA

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13.	Labeling Activity	➢ Improper Labeling in Product.	➢ Improper labeling leads to adverse effect on patient health.	➢ Lack of SOP of Labeling machine ➢ Lack of Line clearance and physical verification. ➢ Lack of proper Dispensing of Packing material.	➢ SOP of labeling machine is in place. ➢ Training imparted to IPQA person for Line clearance and proof check. ➢ SOP of Packing material Dispensing is in place.	Dispensing and Issuance of Packing Material	2	2	1	4	Adequate procedure no recommendation required	NA	NA	NA	NA
14.	Secondary Packing activity	➢ Improper packing of the product.	➢ Improper packing leads to product damage. ➢ Wrong packing leads to risk on patient safety.	➢ Lack of SOP of carton packing ➢ Lack of Line clearance and physical verification. ➢ Lack of proper Dispensing of Packing material.	➢ SOP of operation and cleaning of Hi-cart carton packing machine is in place. ➢ Training imparted to IPQA person for Line clearance and proof check. ➢ SOP of Packing material Dispensing is in place.	Operation and Cleaning of Hi-cart Cartoning Machine	2	2	1	4	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.

Name of Facility/Equipment/Utility/System/Activity/Procedure/Unit Operation: Process Validation For Liquid Injection	**Date:** NA

S. No.	Recommended Action	Responsible Person	Target Date of Completion
1.			
2.			

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CAPA:
If required, mention CAPA No.:

Quality Risk Management Team			Reviewed By Head Operations Sign & Date	Approved By Head QA Sign & Date
Name	**Department**	**Sign & Date**		

QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

Name of Facility/Equipment/Utility/System/Activity/Procedure:	Process Validation Batch of Lidocaine Injection 2%w/v 20 ml Injection

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