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 Pantoprazole Injection	**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*D
1.	Before start of Dispensing	➢ Unapproved material gets dispense ➢ Failed material gets dispense	➢ Unapproved dispense material leads to product contamination. ➢ Fails to achieve the safety, efficacy and quality of product.	➢ Lack of Qualified source of API ➢ 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. ➢ Sterile container in used.	Operation, cleaning, calibration and verification of weighing balance, Dispensing and issuance of RM and PM	2	1	1	2	Adequate procedure no recommendation required	NA	NA	NA	NA

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2.	At 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 and PM SOPs 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 filling. ➢ Check point is in place in BMR to check material is approved/released.	Operation, cleaning, calibration and verification of weighing balance, Dispensing and issuance of RM and PM	3	1	1	3	Adequate procedure no recommendation required	NA	NA	NA	NA

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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, material 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 material hold time is track in BMR.	Operation and Cleaning of Autoclave Cum Bung Processer	1	2	1	2	Adequate procedure no recommendation required	NA	NA	NA	NA

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												S	O	D	RPN S*O*D
4.	Vial washing	➢ Failure in vial washing	➢ Improper vial washing procedure leads to contamination ➢ Due 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. ➢ 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 procedure is in place. ➢ SOP is in place for parameter of utility supply.	Operation and cleaning of vial washing machine	2	1	1	2	Adequate procedure no recommendation required	NA	NA	NA	NA
5.	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 conveyor belt will 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 sterilization & depyrogenation tunnel	2	1	1	2	Adequate procedure no recommendation required	NA	NA	NA	NA

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6.	Filling operation	➢ Failure in filling and stoppering	➢ Improper filling may results in weight 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 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 has been carried out under class A condition (Unidirectional air flow area). ➢ Aseptic intervention has been performed as per media fill protocol and BMR. ➢ Operational training has been done for all concerned persons for aseptic interventions.	Operation and Cleaning of Automatic High speed injectable vial filling and sealing machine	2	1	2	4	If in case any unexpected intervention will happen during batch processing same shall be documented and handled through QMS.	NA	NA	NA	NA

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												S	O	D	RPN S*O*D
7.	Sealing operation	➢ Failure in vial sealing	➢ Improper sealing is not providing leak proof sealing to the vials. ➢ Failure in sealing activity leads to product contaminations.	➢ Unqualified equipment may use. ➢ Operational and cleaning procedure may not available. ➢ Untrained person may operate machine. ➢ Lack of leak test procedure for sealed vials.	➢ Qualification for vial filling and sealing 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 vial.	Operation and cleaning of automatic high speed injectable vial Sealing machine SOP	1	1	1	1	Adequate procedure no recommenda tion required	NA	NA	NA	NA

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												S	O	D	RPN S*O*D
8.	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. ➢ Lack of required lux level.	➢ Visual inspector qualification procedure is in place. ➢ SOP is in place for optical inspection activity. SOP. ➢ 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	2	1	1	2	Adequate procedure no recommendation required	NA	NA	NA	NA
9.	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 (SOP No. SOP/PM/007	1	2	1	2	Adequate procedure no recommendation required	NA	NA	NA	NA

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10.	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	1	2	1	2	Adequate procedure no recommendation required	NA	NA	NA	NA
11.	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	1	1	1	1	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: Process Validation Batch of Pantoprazole Injection	**Date:** NA

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

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		

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QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

Name of Facility/Equipment/Utility/System/Activity/Procedure:	Process Validation Batch of Pantoprazole 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.

Summary & Conclusion: Based upon the risk assessment it is concluded that the existing control measure are sufficient to perform the process validation activity. However the above CAPA action plane the residual risk shall be mitigated and those risk points will not impact the process validation activity.

Verified By
QA
Sign & Date

Approved By
Head QA
Sign & Date