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 Hydrocortisone Sodium Succinate for Injection BP 100 mg	**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, excipients 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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												S	O	D	RPN S*O*D
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. The intervention has been performed in media fill batch. ➢ 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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												S	O	D	RPN S*O*D
6.	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 filling and sealing machine	1	1	1	1	Adequate procedure no recommendation required	NA	NA	NA	NA

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7.	Filling operation	➢ Failure in filling and sealing	➢ Improper filling may results in volume variation. ➢ Improper filling and sealing 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 sealing 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. ➢ Filling duration is mentioned in BMR and same as simulated in media fill.	Operation and Cleaning of Automatic High speed injectable vial filling and sealing machine	2	1	2	4	Adequate procedure no recommendation required	NA	NA	NA	NA

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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. ➢ Visual inspection hood not qualified. ➢ Lack of required lux level.	➢ Visual inspector qualification procedure is in place. ➢ SOP is in place for 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	2	1	1	2	Adequate procedure no recommendation required	NA	NA	NA	NA
9.	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

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10.	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	1	2	1	2	Adequate procedure no recommendation required	NA	NA	NA	NA
11.	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

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 For Liquid 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:	

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