



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 Tranexamic Acid Injection BP 5 ml	Date of Quality Risk Assessment:
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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*D
1.	Before start of Dispensing	<ul style="list-style-type: none"> ➤ Unapproved material gets dispense. ➤ Failed material gets dispense. 	<ul style="list-style-type: none"> ➤ Unapproved dispense material leads to product contamination. ➤ Fails to achieve the safety, efficacy and quality of product. 	<ul style="list-style-type: none"> ➤ Lack of Qualified source of API and excipients. ➤ Lack of testing specification. ➤ Lack of vendor management procedure. 	<ul style="list-style-type: none"> ➤ 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. 	Operation, cleaning, calibration and verification of weighing balance, Dispensing and issuance of RM and PM	4	1	1	4	NA	NA	NA	NA	NA



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2.	At the time of Dispensing	<ul style="list-style-type: none"> ➤ Fails to dispense the required quantity. ➤ Dispense material get contaminate. 	<ul style="list-style-type: none"> ➤ Inadequate result due to improper quantity dispensing and improper testing outcomes (OOS). ➤ Contamination of the area leads to product failure 	<ul style="list-style-type: none"> ➤ 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. 	<ul style="list-style-type: none"> ➤ 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, Cleaning, Calibration and Verification of Weighing Balances, Dispensing and issuance of RM and Dispensing of PM	3	2	1	6	NA	NA	NA	NA	NA



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Unit Operation: Description: The objective of the risk assessment is to evaluate the risk associated during the Process Validation Batch of Tranexamic Acid Injection BP 5 ml

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3.	Component preparation	➤ Failure of Component preparation and sterilization.	➤ Improper cleaning and sterilization of component leads to contamination in product.	<ul style="list-style-type: none"> ➤ 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 	<ul style="list-style-type: none"> ➤ Qualification of sterilizer 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 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 Processor	3	2	1	6	NA.	NA	NA	NA	NA



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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) shall be checked by production person and verified by QA person.	Operation of Integrity Tester	5	1	1	5	NA	NA	NA	NA	NA



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5.	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. ➤ Unsterlized 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. ➤ Micro growth due to utility supply such as WFI, Compressed air and nitrogen.	➤ 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 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. ➤ CIP hold time has been established. ➤ Water system compressed air and Nitrogen are qualified.	Load Cell Verification and Calibration of Manufacturing Vessels CIP of Mixing vessel, Mixing mobile vessel, holding vessel	5	3	1	15	Sample shall be collected for QC analytical and QC microbiological to check the impact of CPP on CQA. CPP and CQA shall be evaluated after completion of process validation activity.	5	1	1	5



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6.	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	5	3	1	15	Sample shall be collected for QC analytical and QC microbiological to check the effect of filtration.	5	1	1	5



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7.	Bulk Hold	➤ Failure in Bulk Hold	➤ During bulk solution hold period Bioburden may increase more than the specification.	<ul style="list-style-type: none"> ➤ 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. ➤ Lacks of established bulk hold time. 	<ul style="list-style-type: none"> ➤ 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. ➤ The procedure is in place filter integrity for vent filter. ➤ Magnehelic guage is there for monitoring the pressure ➤ Training procedure is in place for operation of the vessel. 	Handling of Filters	4	3	2	24	Product hold time shall be establish during process validation batches	5	1	1	5



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8.	Ampoule washing	➤ Failure in Ampoule washing	➤ Improper Ampoule washing procedure leads to contamination ➤ Due improper cleaning particulate matter may presence in Ampoules 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 Ampoule washing machine. ➤ Operational SOP is in place. ➤ Training has been imparted to concerned persons. ➤ A cleaning, operational and preventive maintenance procedure is in place. ➤ SOP is in place for parameter of utility supply.	Operation and Cleaning of Ampoule Washing Machine	5	1	1	5	NA	NA	NA	NA	NA



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9.	Tunnel operation	➤ Failure in Ampoules 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 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 Sterilizing & Depyrogenation Tunnel	5	1	1	5	NA	NA	NA	NA	NA



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10.	Filling operation	➤ Failure in filling and Sealing.	➤ Improper filling may result 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 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 Automatic High Speed Injectable Ampoule Filling and Sealing Machine	5	2	2	20	If in case any unexpected intervention will happen during batch processing same shall be documented and handled through QMS.	5	1	1	5



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11.	Sealing operation	➤ Failure in Ampoule sealing	➤ Improper Sealing is not providing leak proof sealing to the Ampoules. ➤ Failure in sealing activity leads to product contamination.	➤ Unqualified equipment may use. ➤ Operational and cleaning procedure may not available. ➤ Untrained person may operate machine. ➤ Lack of leak test procedure for sealed Ampoules.	➤ Qualification for Ampoule 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 Ampoule.	Operation and Cleaning of Automatic High Speed Injectible Ampoule Filling and Sealing Machine	5	1	1	5	NA	NA	NA	NA	NA



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12.	Visual Inspection	➤ Failure in visual inspection	➤ Improper visual inspection of Ampoules leads to direct impact on product quality and patient safety. ➤ Improper visual inspection to Ampoules 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 Ampoule. ➤ Visual inspection hood not qualified. ➤ Lack of required lux level.	➤ Qualification for Automatic optical inspection machine has been completed ➤ Visual inspector qualification procedure is in place. ➤ SOP is in place for Automatic optical inspection activity. ➤ Inprocess checks is in place for visual inspection activity and AQL is in place.	Operation Cleaning of Automatic Visual Inspection Machine	3	1	5	15	NA	1	1	5	5



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13.	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 good is in place. ➤ Dedicated storage space is available. ➤ Environmental condition is monitoring through BMS.	Handling Of Finished Goods	1	1	5	5	NA	NA	NA	NA	NA
14.	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	1	5	5	NA	NA	NA	NA	NA



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15.	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	1	5	5	NA	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 Tranexamic Acid Injection BP 5 ml
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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