PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

# QUALITY RISK ASSESSEMENT AND MITIGATION PLAN

**QRA No.:**

| **Name of Facility/Equipment/Utility/System/Activity/Procedure**<br>**Unit Operation**: PROCESS VALIDATION | **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-Before start of Dispensing | ➢ Unapproved material gets dispense<br>➢ Failed material get dispense | ➢ Unapproved dispense material leads to product contamination.<br>➢ Fails to achieve the safety, efficacy and quality of product. | ➢ Lack of Qualified source of API and excipient<br>➢ Lack of testing specification.<br>➢ 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.<br>➢ Testing specifications are in place.<br>➢ Vendor management procedure is in place. | Vendor Management | 4 | 1 | 1 | 4 | NA | NA | NA | NA | NA |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | S | O | D | RPN S*O |
| | At time of Dispensing | ➢ Fails to dispense the required quantity.<br>➢ Dispense material get contaminate. | ➢ Inadequate result due to improper quantity dispensing and improper testing outcomes (OOS).<br>➢ Contamination of the area leads to product failure | ➢ Due to selection of wrong capacity weighing balance.<br>➢ Due to lack of operational and calibration procedure of weighing balance.<br>➢ Due to improper environmental conditions.<br>➢ Due to lack of the operation and cleaning procedure for dispensing tools.<br>➢ Due to lack of procedure for dispensing<br>➢ Material dispensed by untrained personnel.<br>➢ No cross check during dispensing<br>➢ Unapproved/rejected material dispensed. | ➢ Selection of weighing balance is depending on balance capacity and quantity of material.<br>➢ SOP is in place for operation and calibration procedure of weighing balances.<br>➢ Environmental condition check point is in place in line clearance checklist.<br>➢ Uses and cleaning of dispensing tool SOP is in place.<br>➢ Dispensing of API, excipient and PM SOPs are in place.<br>➢ Training has been imparted to concerned personnel's.<br>➢ In dispensing activity done by and checked by provision is available in BMR and verification done by before compounding.<br>➢ 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 sterile RM and Dispensing | 3 | 2 | 1 | 6 | NA | NA | NA | NA | NA |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | S | O | D | RPN S*O |
| 2. | Component preparation | ➢ Failure of Component preparation and sterlization. | ➢ Improper cleaning and sterilization of component leads to contamination in product. | ➢ Due to lack of unqualified sterilizer.<br>➢ Lack of component cleaning and component sterilization procedure.<br>➢ Steam lack or utility cut off during sterilization phase.<br>➢ Articles cleaning and sterilization by untrained person.<br>➢ Load pattern may not follow.<br>➢ Selection of wrong recipe.<br>➢ Sensor malfunctioning.<br>➢ Due to sterilization, material hold time cross | ➢ Qualification of sterilizer has been completed.<br>➢ Component cleaning and sterilization SOP is in place.<br>➢ 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.<br>➢ Training has been imparted to all concerned persons.<br>➢ Validated load patterns should be refers before start of activity as per respective SOP.<br>➢ Validated recipe and parameter has been set in autoclave PLC and controlled through password.<br>➢ Defined frequency in place for schedule calibration, Preventive maintenance and validation status.<br>➢ Sterilized hold time has been established and actual material hold time is track in BMR. | Operation and Cleaning of Autoclave Cum Bung Processer | 3 | 2 | 1 | 6 | NA. | NA | NA | NA | NA |

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| | | | | | | | | | | | | S | O | D | RPN S*O |
| 3. | During Filter Integrity testing | ➢ Failure in filter integrity | ➢ Improper filter integrity gets direct impact on sterility of product. | ➢ Unqualified equipment used.<br>➢ Lack of cleaning and operational SOP.<br>➢ Filter integrity activity performed by untrained person.<br>➢ No cross checks provision for filter integrity test report. | ➢ Qualification of filter integrity machine has been completed.<br>➢ Cleaning and Operational SOP is in place<br>➢ Training has been imparted to all concerned persons and user ID given after completion of training.<br>➢ 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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| | | | | | | | | | | | | S | O | D | RPN S*O |
| **4.** | During compounding | ➢ Failure in Batch manufacturing | ➢ Due to improper manufacturing procedure leads to bioburden may increase more than specification.<br>➢ Unexpected outcome like yield and concentration of product leads to product failure. | ➢ Compounding procedure not available.<br>➢ Due to lack of calibration ,preventive maintenance, operational and cleaning procedures.<br>➢ Qualification of vessel system not available.<br>➢ Unsterlized and unclean equipment may use.<br>➢ Inadequate cleaning or equipment's difficult to clean.<br>➢ Compounding activity handle by untrained person.<br>➢ Due to lack of clean equipment hold time may cross.<br>➢ Micro growth due to utility supply such as WFI, Compressed air and nitrogen. | ➢ Detail, compounding procedure is in place in BMR.<br>➢ Vessel calibration, preventive maintenance, operational and cleaning procedure are in place.<br>➢ Qualification of vessels system is completed.<br>➢ In line clearance of compounding activity ensure the sterilization vessels shall be mention in BMR.<br>➢ Vessels CIP, SIP procedure are qualified and SOP is in place.<br>➢ Training has been completed for all concerned persons.<br>➢ CIP hold time has been established.<br>➢ Water system compressed air and Nitrogen are qualified. | Load Cell Verification and Calibration of Manufacturing Vessels<br>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.<br>CPP and CQA shall be evaluated after completion of process validation activity. | 5 | 1 | 1 | 5 |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | S | O | D | RPN S*O |
| **5.** | Filtration activity | ➢ Failure in filtration of bulk solution | ➢ Filtrate is not sterile leads to microbial growth.<br>➢ Improper filtration leads to contamination in product. | ➢ Lack of procedure for sterilization of filter.<br>➢ Lack of procedure to check the filter integrity.<br>➢ Due to improper training to concerned persons.<br>➢ Lack of filtration procedures. | ➢ SOP is in place for SIP of vessel system along with product transfer line.<br>➢ Filter integrity procedure is in place check points is available.<br>➢ Training procedures is in place.<br>➢ 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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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | S | O | D | RPN S*O |
| **6.** | Bulk Hold | ➢ Failure in Bulk Hold | ➢ During bulk solution hold period bioburden may increase more than the specification. | ➢ Lack of qualification of vessel system.<br>➢ Lack of aseptic connection.<br>➢ Lack of positive pressure.<br>➢ Due to failure of filter integrity of vent filters.<br>➢ Lack of provision to monitor the pressure in vessel.<br>➢ Due to activity handle by untrained person.<br>➢ Lack of established bulk hold time. | ➢ Qualification of the vessel system has been completed.<br>➢ Aseptic connection for filtration is defined in BMR.<br>➢ 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.<br>➢ The procedure is in place for pre and post filter integrity for vent filter.<br>➢ Magnehelic guage is there for monitoring the pressure<br>➢ Training procedure is in place for operation of the vessel. | Handling of Filters | 5 | 3 | 2 | 30 | Product hold time shall be establish during process validation batches. | 5 | 1 | 1 | 5 |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | S | O | D | RPN S*O |
| 7. | Vial washing | ➢ Failure in vial washing | ➢ Improper vial washing procedure leads to contamination<br>➢ Due improper cleaning particulate matter may presence in vials and leads to failure in visual inspection. | ➢ Lack of qualified equipment.<br>➢ Lack of operational procedure.<br>➢ Due to activity handled by untrained person.<br>➢ Due to lack of cleaning operation and preventive maintenance procedure.<br>➢ Due to improper utility supply. | ➢ Qualification has been completed for vial washing machine.<br>➢ Operational SOP is in place.<br>➢ Training has been imparted to concerned persons.<br>➢ Cleaning, operational and preventive maintenance procedures is in place.<br>➢ SOP is in place for parameter of utility supply. | Operation and Cleaning of Vial Washing Machine | 5 | 1 | 1 | 5 | NA | NA | NA | NA | NA |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | S | O | D | RPN S*O |
| **8.** | Tunnel operation | ➢ Failure in vials depyrogenation. | ➢ Improper depyrogenation leads BET and sterlity Failure.<br>➢ Failure in tunnel leads to loss of time and resources. | ➢ Unqualified equipment may use.<br>➢ Lack of cleaning and operational procedure.<br>➢ Untrained person may operate machine<br>➢ Tunnel temperature and DP fluctuation during batch activity<br>➢ Selection of wrong parameters and recipe<br>➢ Sensor malfunctioning. | ➢ Qualification has been completed for tunnel.<br>➢ Operational SOP is in place.<br>➢ Training has been imparted to concerned persons.<br>➢ Cleaning SOP is in place.<br>➢ Tunnel conveyer belt will stop automatically if sensor temperature goes out of set point. The intervention has been performed in media fill batch.<br>➢ Defined frequency is in place for schedule calibration, temperature sensor, Preventive maintenance and validation status of tunnel sterilizer.<br>➢ Validated recipe and parameter is in place. | Operation of Cleaning of Sterilizing & Depyrogenation Tunnel | 5 | 2 | 2 | 20 | | 5 | 1 | 1 | 5 |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | S | O | D | RPN S*O |
| **9.** | Filling operation | ➢ Failure in filling and stoppering | ➢ Improper filling may result in volume variation.<br>➢ Improper filling and stoppering activity may leads to contamination. | ➢ Lack of qualification procedure.<br>➢ Lack of cleaning and operational procedure.<br>➢ Unsterile parts or article may use I filling operation.<br>➢ Lack of environmental condition for filling.<br>➢ Improper handling of aseptic intervention may lead to product contamination.<br>➢ Operation handled by untrained and unqualified person.<br>➢ Due aseptic interventions<br>➢ Due filling duration. | ➢ Qualification of filling and stoppering machine has been completed.<br>➢ SOP for filling machine cleaning and operation is in place.<br>➢ Sterilization procedure for machine parts loads is in place.<br>➢ Filling shall be carried out under class A condition(Unidirectional air flow area)<br>➢ Aseptic intervention shall be performed as per media fill protocol and BMR.<br>➢ Operational training has been done for all concerned persons for aseptic.<br>➢ Filling duration is mentioned in BMR and same was simulated in media fill. | Operation and Cleaning of Automatic High Speed Injectable Powder Filling and Stoppering 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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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | S | O | D | RPN S*O |
| **10.** | Capping operation | ➢ Failure in vial sealing | ➢ Improper crimping is not providing leak proof sealing to the vials.<br>➢ Failure in capping activity leads to product contamination. | ➢ Unqualified equipment may use.<br>➢ Operational and cleaning procedure may not available.<br>➢ Untrained person may operate machine.<br>➢ Lack of leak test procedure for sealed container. | ➢ Qualification for capping machine has been completed.<br>➢ Operational and cleaning SOP is in place.<br>➢ Training has imparted to concerned persons.<br>➢ SOP is in place for leak test for sealed vial and container closer integrity test has been established in media fill batch. | Operation & Cleaning of Filling, Dropper Fixing & Screw Capping Machine | 5 | 1 | 1 | 5 | NA | NA | NA | NA | NA |

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| | | | | | | | | | | | | S | O | D | RPN S*O |
| **11.** | Visual Inspection | ➢ Failure in visual inspection | ➢ Improper visual inspection of vials leads to direct impact on product quality and patient safety.<br>➢ Improper visual inspection to vials gets market complaints to the organization. | ➢ Lack of qualification procedure for visual inspector.<br>➢ Lack of SOP for visual inspection procedure.<br>➢ Visual inspection activity done by unqualified person.<br>➢ Lack of cross check procedure for inspected vial.<br>➢ Visual inspection hood not qualified.<br>➢ Lack of required lux level. | ➢ Visual inspector qualification procedure is in place.<br>➢ SOP is inplace for Automatic optical inspection activity.<br>➢ Qualification has been completed for concerned persons.<br>➢ 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 |
| **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.<br>➢ Chance of product degradation due to irrespective storage condition. | ➢ Lack of SOP<br>➢ Lack of dedicated storage space<br>➢ Due to environmental condition not maintain. | ➢ SOP for handling of finished good is in place.<br>➢ Dedicated storage space is available.<br>➢ Environmental condition is monitoring through BMS. | Handling Of Finished Goods | 1 | 1 | 5 | 5 | NA | NA | NA | NA | NA |

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| | | | | | | | | | | | | S | O | D | RPN S*O |
| **13.** | Labelling Activity | ➢ Improper Labelling in Product. | ➢ Improper labeling leads to adverse effect on patient health. | ➢ Lack of SOP of Labeling machine<br>➢ Lack of Line clearance and physical verification.<br>➢ Lack of proper Dispensing of Packing material. | ➢ SOP of labeling machine is in place.<br>➢ Training imparted to IPQA person for Line clearance and proof check.<br>➢ SOP of Packing material Dispensing is in place. | Dispensing and Issuance of Packing Material | 1 | 1 | 5 | 5 | NA | NA | NA | NA | NA |
| **14.** | Secondary Packing activity | ➢ Improper packing of the product. | ➢ Improper packing leads to product damage.<br>➢ Wrong packing leads to risk on patient safety. | ➢ Lack of SOP of carton packing<br>➢ Lack of Line clearance and physical verification.<br>➢ Lack of proper Dispensing of Packing material. | ➢ SOP of operation and cleaning of Hi-cart carton packing machine is in place.<br>➢ Training imparted to IPQA person for Line clearance and proof check.<br>➢ 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 |

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**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: Purified water generation & distribution system** | | Date: | |
|---|---|---|---|
| **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 Equipment:** |
|---|

**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**