# Risk Assessment

# For

# Vial Depyrogenation Tunnel

| Activity | Name | Date | Signature |
|---|---|---|---|
| **Prepared** | | | |
| **Reviewed** | | | |
| **Approved** | | | |

# RISK ASSESSMENT FOR VIAL DEPYROGENATION TUNNEL

## 1 Purpose of the Risk Assessment

At the very basic stage of design the Risk Assessment is carried out to verify that all features are taken into consideration to avoid the risk of failure of critical GMP and EHS parameter in the equipment.

During study, all GMP, EHS and operational parameters will be identified and assessed for the risk, appropriate mitigation will be proposed and verification point will be identified and defined.

The Risk Assessment report is produced to provide the documented evidence that design concepts or requirement are complete in considering all GMP, EHS and operational risks.

## 2 Background

Risk Assessment shall be prepared for the Vial Depyrogenation Tunnel as Vial Depyrogenation Tunnel will be installed in the existing sterile formulation facility.

## 3 Actions generated from Risk Assessment

[Comment: Mention here the actions generated from Risk Management process as a Risk Reduction process]

| S.No. | Action | Responsible/Due Date | Department |
|---|---|---|---|
| | | | |

## 4 Risk Communication:

Risk shall be communicated to Quality Assurance, Engineering and User (system owner) department.

## 5 Risk Review:

| S.No. | Document Name | Document Number | Outcome of the review |
|---|---|---|---|
| | | | |

[Comment: Mention the previous risk assessments report/document numbers for the same product/document/equipment/area/topic, identified from risk assessment report log].

## 6 Attachments

NA

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## 7 Detailed Risk Assessment process for qualitative approach

| S.No. | Process step / influencing factor/ Component | Risk Possible Failure | Evaluation GMP relevant Yes/ No | Justification Explanation | Other Risk type | Justification Explanation | Risk Level High/ Medium/ Low | Mitigation action plan | Residual Risk level Acceptable & Not Acceptable |
|---|---|---|---|---|---|---|---|---|---|
| **Input & Charging** | | | | | | | | | |
| **1.** | Vial size | Equipment not suitable for different size of Vials | No | NA | Operational | Different Vial sizes may not be processed with same equipment. | Medium | Verification shall be performed at the time of qualification activities | Acceptable |
| **2.** | Transport of Vials | ▪ Vials incorrect motion on the transport belt.<br>▪ Infeed guide to tunnel not properly aligned with Vial Washing machine. | Yes | Vial jamming, Vial rupture, Vial cosmetic damage may take place. | No | NA | High | ▪ Functionality shall be checked at the time of qualification activities<br>▪ The level of the infeed guide to tunnel shall be at the same level of Vial washing machine out feed. | Acceptable |
| **3.** | Transport of vials | Abrasion of vials due to attrition with the conveyor side walls. | Yes | Damage to vials | No | NA | High | ▪ MOC of the side walls of the conveyor shall be GMP compliant & with smooth surface finish.<br>▪ The suitability of the materials shall be proven by certificate/ manufacturers declarations | Acceptable |
| **4.** | Transport of vials | No vials at infeed of tunnel | Yes | Tunnel may run without any vials. Downstream equipment functioning may be hampered. | No | NA | High | The tunnel conveyor should stop in case of minimum load at infeed. | Acceptable |
| **5.** | Transport of vials | High/ low transport belt speed | Yes | Improper depyrogenation; damage to vials | No | NA | High | The control system shall have suitable mechanism to ensure desirable speed is maintained, against set value with feedback of actual speed. | Acceptable |

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| **6.** | Transport of vials | Frequent stopping of tunnel due to no vials at infeed. | Yes | Depyrogenation process and downstream equipment functioning shall be hampered. | No | NA | High | Speed synchronization between Vial washing machine and tunnel shall be carried out and proper connectivity should be established and qualified. | Acceptable |
| **7.** | Transport of Vials | Un-dried Vials enter the heating zone of tunnel directly. | Yes | Vials with moisture when exposed to very high temperature may break. | No | NA | High | Functionality shall be verified during execution of qualification studies | Acceptable |
| **Process** | | | | | | | | | |
| **8.** | Air Supply (Drying, Depyrogenation & Cooling zone) | Inadequate air quality | Yes | Particle laden air may enter chamber and lead to Vial contamination. | No | NA | High | Monitoring of the nonviable particle concentration in tunnel during qualification. | Acceptable |
| **9.** | Air Supply (Drying, Depyrogenation & Cooling zone) | Choking/ Leakage in HEPA filter | Yes | ▪ Non-uniform air distribution leading to improper depyrogenation.<br>▪ Contamination of Vials due to particle laden air. | No | NA | High | ▪ Integrity test of HEPA filters shall be performed during qualification.<br>▪ Integrity testing shall also be performed at regular intervals as per SOP. | Acceptable |
| **10.** | Air Supply (Drying, Depyrogenation & Cooling zone) | HEPA filter integrity cannot be performed. | Yes | Integrity checking is a GMP requirement. | No | NA | High | Functionality shall be verified during execution of qualification studies | Acceptable |
| **11.** | Air Supply (Drying, Depyrogenation & Cooling zone) | High temperature in depyrogenation zone may damage HEPA filter or affect its efficiency. | Yes | Damage to HEPA filter may lead to contamination of Vials | No | NA | High | Heater ON/ OFF action shall be interlocked with the operation of blowers to safeguard HEPA filters. | Acceptable |

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| **12.** | Air Supply (Drying, Depyrogenation & Cooling zone) | Non-unidirectional air distribution | Yes | Unidirectional airflow is requirement for Grade A classification level | No | NA | High | Smoke study shall be carried out during qualification to demonstrate unidirectional air flow. | Acceptable |
| **13.** | Air flow | Inadequate air flow inside all 3 zones. | Yes | Improper Vial sterilization & depyrogenation | No | NA | High | Functionality shall be verified during execution of qualification studies | Acceptable |
| **14.** | Air velocity | Air velocity not adequate | Yes | Air flow will be disturbed; Unidirectional air flow shall not be maintained up to conveyor level. | No | NA | High | ▪ Adequate air velocity shall be maintained below the HEPA filters in all 3 zones, so as to maintain unidirectional air flow.<br>▪ Verification of air velocity performed during qualification | Acceptable |
| **15.** | Air flow | Once through system is installed for all 3 zones i.e. entire supply air from all 3 zones is exhausted out without recirculation. | Yes | Ineffective heating or cooling in respective zone. | Energy loss | Too much energy shall be consumed in heating or cooling fresh air. | High | Functionality shall be verified during execution of qualification studies | Acceptable |
| **16.** | Conveying | Conveyor belt speed low/ high | Yes | Improper residence time affects the validated depyrogenation cycle. | No | NA | High | Verification of accuracy of conveyor speed during qualification | Acceptable |
| **17.** | Vial Transport | Internal or outfeed gates opening low. | Yes | Depyrogenation of different sizes of Vials not possible. | No | NA | High | Functionality shall be verified during execution of qualification studies | Acceptable |
| **18.** | Vial Transport | Internal or out feed gates openings too wide; No control on gate position | Yes | Inadequate temperature distribution inside tunnel zones. | No | NA | High | Alarm shall be provided in case of malfunction of gates or sensor faulty | Acceptable |

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| **19.** | Exhaust | Air extraction flow too high; Exhaust air too hot. | Yes | Inadequate temperature distribution inside depyrogenation zone. | No | NA | High | Suitable system shall be provided to regulate the exhaust air flow from the depyrogenation chamber so as to ensure effective heating of Vials. | Acceptable |
| **20.** | Vial transport | Differential pressure between different zones cannot be maintained | Yes | ▪ Inadequate temperature distribution inside tunnel<br>▪ May lead to contamination of sterile, depyrogenated Vials. | No | NA | High | ▪ Smoke study shall be performed during qualification to demonstrate differential pressure.<br>▪ Alarm shall be provided in case the differential pressure between zones goes out of limit | Acceptable |
| **21.** | Heating | Low temperature inside the drying zone. | Yes | Inadequate Vials drying | No | NA | High | ▪ Alarm shall be provided in case heating system not working/ faulty.<br>▪ Routine maintenance of heating system shall be carried out as per preventive maintenance SOP. | Acceptable |
| **22.** | Heating | High temperature inside the depyrogenation zone | Yes | Vial damage or rupture; HEPA filter burning | No | NA | High | Frequent checking of the wear and tear of the heating element as per preventive maintenance SOP. | Acceptable |
| **23.** | Heating | Low temperature inside the depyrogenation zone. | Yes | Inadequate Vials sterilization & depyrogenation. | No | NA | High | ▪ Alarm provision in case heating system faulty.<br>▪ Routine maintenance of heating system shall be carried out as per preventive maintenance SOP | Acceptable |

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| **24.** | Heating | Heat distribution profile (ventilation) not proper. | Yes | Inhomogeneous distribution of air, depyrogenation not reproducible | No | NA | High | ▪ Temperature mapping shall be performed during qualification.<br>▪ Tunnel should be capable to reduce the endotoxin load in the Vial by more than 3 log. | Acceptable |
| **25.** | Cooling of Vials | Vials temperature at out feed of cooling zone too high | Yes | Chances of Vial damage due to rapid change in temperature. | No | NA | High | Conveyor belt should stop in case set cooling temperature is not achieved. | Acceptable |
| **26.** | Cooling of Vials | ▪ Chilled water low/ no flow<br>▪ High temperature chilled water supply | Yes | Cooling zone temperature shall not be maintained; Vial temperature high. | No | NA | High | Functionality shall be verified during execution of qualification studies | Acceptable |
| **27.** | Cooling | Heat exchanger damage/ choking/ not working | Yes | Cooling of the Vial inadequate | No | NA | High | Chilled water coil cleaning will be performed at regular intervals as per SOP for preventive maintenance. | Acceptable |
| **28.** | Compressed air | Insufficient/ No pressure | Yes | Equipment operation will be disturbed | No | NA | High | Functionality shall be verified during execution of qualification studies | Acceptable |
| **Discharge** | | | | | | | | | |
| **29.** | Output from Tunnel | Output of depyrogenation tunnel is not synchronized with filling machine. | No | No impact on depyrogenation process | Operational | Proper flow of the Vials gets disturbed. | Medium | Co-ordination between each of these modules shall be carried-out and proper connectivity shall be established and qualified. | Acceptable |
| **30.** | Out feed | Maximum accumulation at out feed buffer rotary plate. | No | No impact on depyrogenation process | Operational | Vials may fall off due to high accumulation at out feed | High | Tunnel conveyor shall stop in case out feed is full. | Acceptable |
| **Equipment Construction- Internal Surface** | | | | | | | | | |

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| **31.** | Metallic components in direct contact with Vials | The material may not be suitable; may contaminate Vials during sterilization | Yes | MOC not resistant - Interaction with media possible | No | NA | High | The suitability of the materials shall be proven by certificate/ manufacturers declarations | Acceptable |
| **32.** | Polymeric materials | Polymeric materials are not compatible and are not replaceable | Yes | Shall lead to contamination of Vials. | No | NA | High | • Food grade polymeric material certificate/ declaration have to be provided by vendor<br>• The easy change of gaskets should be possible. | Acceptable |
| **33.** | Welding Joints | Weld joints not grounded properly and are not passivated | Yes | Uneven and improperly ground weld joints will form a space for dust accumulation. | No | Na | High | Weld reports/ certificate/ declaration have to be provided by vendor. | Acceptable |
| **34.** | Metallic contact parts. | Internal surface finishing insufficient | Yes | May lead to improper cleaning of the surface which will lead to microbial growth hence Vial contamination | No | NA | High | The suitability of the materials & roughness, Ra ≤ 0.8 µm shall be proven by certificate/ manufacturers declarations. | Acceptable |
| **35.** | Insulation | Material not suitable | Yes | Leads to contamination | No | NA | High | Functionality shall be verified during execution of qualification studies | Acceptable |
| **Equipment Construction- External Surface** | | | | | | | | | |
| **36.** | Surface | External surface of equipment is not suitable | Yes | May lead to the clean room contamination | No | NA | Medium | The suitability of the materials shall be proven by certificate/ manufacturers declarations. | Acceptable |
| **37.** | Finishing | External finish of equipment is not proper. | Yes | May lead to the microbial growth | No | NA | Medium | External surface should be free from sharp edges, corners, crevices etc., all metallic external surface shall be matt or mirror finished. | Acceptable |

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| **Cleaning** | | | | | | | | | |
| **38.** | Cleaning | Difficult cleaning | Yes | Accumulation of particles, contamination of clean room possible | No | NA | High | • Parts which are required for cleaning shall be provided with quick fixing arrangement<br>• The design of the complete equipment shall ensure adequate clean ability (smooth, SS 316 or better surface). | Acceptable |
| **39.** | Labeling of components | Labeling of components/ media inappropriate | Yes | Prerequisite for qualification &maintenance | No | NA | Medium | • Labels affixed on the equipment should be heat resistant.<br>• All labelling shall be done in English language and according to P&ID | Acceptable |
| **PLC/ Control System** | | | | | | | | | |
| **40.** | Process automation | Process parameters are not controlled automatically. | Yes | Possibility of human error leads to a process which is not validated | No | NA | High | The equipment shall control & detect failure mode automatically. | Acceptable |
| **41.** | Man-machine Interface | Process / process status not visible for operating personnel. | Yes | Operating personnel must have knowledge on the process status | No | NA | High | NA | Acceptable |
| **42.** | Man-machine Interface | Display language not identified. | Yes | Pre-requisite for the GMP compliant operation | No | NA | High | The language on the display of MMI shall be English language | Acceptable |
| **43.** | Man-machine Interface | Monitoring of GMP relevant data not possible | Yes | Basic GMP requirement | No | NA | High | Monitoring of GMP relevant data should be possible | Acceptable |

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| **44.** | Man-machine Interface | Recorder failure | Yes | Basic GMP requirement; Critical process parameters & batch report might not be saved and printed. | No | NA | High | • Diagnostic function test for the same shall be carried out as part of qualification activity.<br>• Routine backup for process data shall be performed as per SOP. | Acceptable |
| **45.** | PLC/ Control system | Control system does not detect failures and generate alarms | Yes | Process optimization and validation is not possible | No | NA | High | • Batch records / print outs shall be defined during qualification.<br>• Failure of set parameters should get indicated as alarms and necessary interlocks should be in place. | Acceptable |
| **46.** | PLC / Control system | Status parameters not clear | Yes | Process for the particular product at particular stage can't be regulated easily. | No | NA | High | Verification shall be performed at the time of qualification activities. | Acceptable |
| **47.** | PLC / Control system | Power failure/ emergency stop | Yes | Process out of specification | Safety | Unsafe if start automatically on restoration of power | High | • SOP for "Operation, cleaning and Maintenance of Vial Depyrogenation Tunnel" should mention action to be taken in case of power failure.<br>• Operator settings shall remain unchanged and restored after emergency stop/power failure.<br>• Provision of UPS to the control system. | Acceptable |
| **48.** | PLC / Control system | Malfunction of control system | Yes | Correct function of control system is a basic requirement for GMP-compliant operation | No | NA | High | • Input/Output test implementation during qualification activities<br>• Control system software backup should be provided by the vendor. | Acceptable |

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| **49.** | Accessibility to PLC | Parameter settings not identified universally | Yes | Basic GMP requirement | No | NA | High | Parameters settings shall be in numeric only. | Acceptable |
| **50.** | PLC / Control system | Time measurement works incorrect | Yes | Process cannot be carried out using validated parameters. | No | NA | High | • Time verification of the system clock shall be performed at frequent intervals as per SOP.<br>• PLC Clock verification shall be performed during qualification. | Acceptable |
| **51.** | PLC / Control system | No protection of PLC against manipulation & changes. | Yes | Basic GMP requirement. | No | NA | High | • All users shall be provided with unique passwords.<br>• System shall allow only authorized users to access system and change parameters. | Acceptable |
| **52.** | PLC/ Control System | Wrong programs<br>(Not appropriate for the designated process) | Yes | Process out of specification | No | NA | High | • Verification of correct program, set values during qualification.<br>• List of all process relevant parameters including related, programmed limits shall be described in SOP. | Acceptable |
| **Measuring Instruments** | | | | | | | | | |
| **53.** | Measuring Instruments | Measuring instruments not suitable | Yes | Improper measurements | No | NA | High | Operational range of Measuring Instruments > equipment's working range. | Acceptable |

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| **54.** | Measuring instruments | Measuring instruments not calibrated and not suitable for re-calibration | Yes | Non calibrated measuring instruments may lead to false machine functions | No | NA | High | Test certificate shall be verified during execution of qualification studies | Acceptable |
| **55.** | GMP relevant measurement instruments | Instruments cannot be dismounted | Yes | Defective instruments must be dismounted for exchange and calibration | No | NA | High | • Mounting of instruments should give the possibility for dismounting and replacement<br>• Constructional solution: easy access for re-calibration activities shall be provided. | Acceptable |
| **Maintenance** | | | | | | | | | |
| **56.** | Maintenance | Malfunctions due to worn parts | Yes | Basic GMP requirement | No | NA | High | • The unit should contain necessary protection devices to ensure that the equipment & the article remain in a safe condition.<br>• Preventive maintenance SOP shall be prepared<br>• Machine shall be easy to maintain. | Acceptable |
| **57.** | Motors | Motors failure | Yes | Depyrogenation process may be affected | No | NA | High | Preventive maintenance of motors shall be carried out at regular intervals as per SOP. | Acceptable |
| **Environment & Safety** | | | | | | | | | |
| **58.** | Electrical system | • Electrical systems are not verified for safety.<br>• Earthing not provided for equipment. | No | It will not affect the sterilization process | EHS | May lead to an accident | Medium | • All electrical systems shall be tested for safety and shall be provided with safety markings e.g. C.E. marking.<br>• Electrical parts shall be covered. Proper earthing shall be provided for the equipment. | Acceptable |

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| **59.** | Emergency stop | Instantaneous stopping of the equipment not possible | No | Does not have any impact on quality of the product | EHS | Emergency stop function is required for equipment, personnel and product protection | High | Verification shall be performed at the time of qualification activities. | Acceptable |
| **60.** | Noise level | More noise is produced by the equipment during the operation. | No | Does not have any impact on quality of the product | EHS | High noise may cause deafness and anxiety | Medium | Verification shall be performed at the time of qualification activities. | Acceptable |
| **61.** | Moving & electrical parts | Moving & electrical parts are not covered. | No | Does not have any impact on quality of the product | EHS | Operator safety | Medium | Verification shall be performed at the time of qualification activities | Acceptable |
| **62.** | Heating | High emission of heat leading to disturbance of clean room conditions | Yes | Strong heat transfer might cause high room temperature air turbulence which might have adverse effects on the clean room environment | EHS | Environment & Personnel safety hazards | High | ▪ Warning sticker should be provided on hot surfaces.<br>▪ Insulation material should be resin bounded Glass wool / Rock wool. | Acceptable |
| **63.** | Classification Level | Cooling zone does not maintain Grade A when tunnel is off at night and during holidays | Yes | Contamination of Vials in the cooling zone | No | NA | High | Verification shall be performed at the time of qualification activities | Acceptable |
| **Documentation** | | | | | | | | | |
| **64.** | User | Faulty operation & maintenance | Yes | SOPs are basic GMP-requirement | No | NA | High | ▪ All end-users have to be trained on SOPs<br>▪ Training of SOPs has to be documented<br>▪ Training on the job of end users by vendor<br>▪ Training on operation, troubleshooting & maintenance related activities. | Acceptable |

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| **65.** | User | Operation SOP does not contain proper information and user may operate system | Yes | User may make a wrong decision. | No | NA | High | • System operation SOP must be reviewed with all aspects and approved.<br>• Vendor shall provide execution support to the user to complete all stages of the qualification report. | Acceptable |
| **66.** | User | Unauthorized person tries to start/stop the system | Yes | Untrained persons may damage the system or product quality may be affected. | No | NA | High | Key switch should be provided for operation of the system | Acceptable |
| **67.** | Vendor | Technical documentation from vendor not adequate | Yes | Adequate technical documentation is basic GMP requirement | No | NA | High | Verification of documents shall be performed at the time of qualification activities | Acceptable |