



RISK ASSESSMENT FOR VIAL DEPYROGENATION TUNNEL

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

7 Detailed Risk Assessment process for qualitative approach



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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	<ul style="list-style-type: none"> ▪ Vials incorrect motion on the transport belt. ▪ 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	<ul style="list-style-type: none"> ▪ Functionality shall be checked at the time of qualification activities ▪ The level of the infeed guide to tunnel shall be at the same level of Vial washing machine out feed. 	Acceptable



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3.	Transport of vials	Abrasion of vials due to attrition with the conveyor side walls.	Yes	Damage to vials	No	NA	High	<ul style="list-style-type: none"> MOC of the side walls of the conveyor shall be GMP compliant & with smooth surface finish. 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



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9.	Air Supply (Drying, Depyrogenation & Cooling zone)	Choking/ Leakage in HEPA filter	Yes	<ul style="list-style-type: none"> Non-uniform air distribution leading to improper depyrogenation. Contamination of Vials due to particle laden air. 	No	NA	High	<ul style="list-style-type: none"> Integrity test of HEPA filters shall be performed during qualification. 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	<ul style="list-style-type: none"> Adequate air velocity shall be maintained below the HEPA filters in all 3 zones, so as to maintain unidirectional air flow. Verification of air velocity performed during qualification 	Acceptable



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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	<ul style="list-style-type: none"> ▪ Inadequate temperature distribution inside tunnel ▪ May lead to contamination of sterile, depyrogenated Vials. 	No	NA	High	<ul style="list-style-type: none"> ▪ Smoke study shall be performed during qualification to demonstrate differential pressure. ▪ Alarm shall be provided in case the differential pressure between zones goes out of limit 	Acceptable



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21.	Heating	Low temperature inside the drying zone.	Yes	Inadequate Vials drying	No	NA	High	<ul style="list-style-type: none"> Alarm shall be provided in case heating system not working/ faulty. 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	<ul style="list-style-type: none"> Alarm provision in case heating system faulty. 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	<ul style="list-style-type: none"> Temperature mapping shall be performed during qualification. 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	<ul style="list-style-type: none"> Chilled water low/ no flow 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



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28.	Compressed air	Insufficient/ pressure	No 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									
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



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32.	Polymeric materials	Polymeric materials are not compatible and are not replaceable	Yes	Shall lead to contamination of Vials.	No	NA	High	<ul style="list-style-type: none"> Food grade polymeric material certificate/ declaration have to be provided by vendor 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



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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
Cleaning									



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38.	Cleaning	Difficult cleaning	Yes	Accumulation of particles, contamination of clean room possible	No	NA	High	<ul style="list-style-type: none"> Parts which are required for cleaning shall be provided with quick fixing arrangement 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	<ul style="list-style-type: none"> Labels affixed on the equipment should be heat resistant. 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



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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
44.	Man-machine Interface	Recorder failure	Yes	Basic GMP requirement; Critical process parameters & batch report might not be saved and printed.	No	NA	High	<ul style="list-style-type: none"> Diagnostic function test for the same shall be carried out as part of qualification activity. Routine backup for process data shall be performed as per SOP. 	Acceptable



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45.	PLC/ Control system	Control system does not detect failures and generate alarms	Yes	Process optimization and validation is not possible	No	NA	High	<ul style="list-style-type: none">• Batch records / print outs shall be defined during qualification.• 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



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47.	PLC / Control system	Power failure/ emergency stop	Yes	Process out of specification	Safety	Unsafe if start automatically on restoration of power	High	<ul style="list-style-type: none"> SOP for “Operation, cleaning and Maintenance of Vial Depyrogenation Tunnel” should mention action to be taken in case of power failure. Operator settings shall remain unchanged and restored after emergency stop/ power failure. 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	<ul style="list-style-type: none"> Input/ Output test implementation during qualification activities 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	<ul style="list-style-type: none">• Time verification of the system clock shall be performed at frequent intervals as per SOP.• 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	<ul style="list-style-type: none">• All users shall be provided with unique passwords.• System shall allow only authorized users to access system and change parameters.	Acceptable



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52.	PLC/ Control System	Wrong programs (Not appropriate for the designated process)	Yes	Process out of specification	No	NA	High	<ul style="list-style-type: none"> • Verification of correct program, set values during qualification. • 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
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



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55.	GMP relevant measurement instruments	Instruments cannot be dismantled	Yes	Defective instruments must be dismantled for exchange and calibration	No	NA	High	<ul style="list-style-type: none"> Mounting of instruments should give the possibility for dismantling and replacement 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	<ul style="list-style-type: none"> The unit should contain necessary protection devices to ensure that the equipment & the article remain in a safe condition. Preventive maintenance SOP shall be prepared Machine shall be easy to maintain. 	Acceptable



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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	<ul style="list-style-type: none"> Electrical systems are not verified for safety. Earthing not provided for equipment. 	No	It will not affect the sterilization process	EHS	May lead to an accident	Medium	<ul style="list-style-type: none"> All electrical systems shall be tested for safety and shall be provided with safety markings e.g. C.E. marking. Electrical parts shall be covered. Proper earthing shall be provided for the equipment. 	Acceptable
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



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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	<ul style="list-style-type: none"> ▪ Warning sticker should be provided on hot surfaces. ▪ 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



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64.	User	Faulty operation & maintenance	Yes	SOPs are basic GMP-requirement	No	NA	High	<ul style="list-style-type: none"> ▪ All end-users have to be trained on SOPs ▪ Training of SOPs has to be documented ▪ Training on the job of end users by vendor ▪ Training on operation, troubleshooting & maintenance related activities. 	Acceptable
65.	User	Operation SOP does not contain proper information and user may operate system	Yes	User may make a wrong decision.	No	NA	High	<ul style="list-style-type: none"> • System operation SOP must be reviewed with all aspects and approved. • 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



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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