Risk Assessment Document
For
Ampoule Depyrogenation Tunnel

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RISK ASSESSMENT FOR AMPOULE DEPYROGENATION TUNNEL

1 Introduction

According to the definition, given in Annex 15 to the EU-GMP-Guide, a Risk Assessment is a method to assess and characterize the critical parameters in the functionality of an equipment or process. Therefore, risk assessment is a key element in the qualification and validation approach.

In the project context, risk assessment for the equipment is performed as basic GMP/ EHS-Risk Assessment, which shall help to identify important GMP/ EHS-requirements.

2 Aim of 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.

3 Reference Documents/ Drawings

S.No.	Document Title	Document Number
1.	Validation master plan	

4 Equipment/ System Description

This risk assessment is conducted for Ampoule Depyrogenation Tunnel which shall be installed at the downstream of Ampoule washing machine and its movement shall be synchronized with the Ampoule Washing machine. The machine shall consist of following main components in order to run smoothly:

a) Conveying System: For transport of Ampoules through depyrogenation tunnel i.e. from washing to filling machine through tunnel
b) Infeed (Drying) zone with HEPA: For drying the washed Ampoules with HEPA filtered air.
c) Heating (Depyrogenating) zone with HEPA: For sterilizing & depyrogenating the Ampoules with circulation of HEPA filtered hot air.
d) Cooling zone with HEPA: For cooling the Ampoules with circulation of HEPA filtered cool air.

The Depyrogenation tunnel shall be fully automatic running equipment. All the requirements of regulatory authority shall be complied by the equipment. The washed ampoules from Ampoule Washing machine shall be transferred to the tunnel by the conveying system. The Tunnel shall be designed to produce the depyrogenating condition by achieving a temperature of more than 300^0C. The process shall be capable of providing more than three-log reduction of Endotoxins in the Ampoules. The system shall maintain a uniform temperature inside the tunnel. The conveyor transport the Ampoules from the tunnel to the filling area through the drying, depyrogenating and cooling zone.

Most of the possible risk concerning the handling/ operation of the Ampoule Depyrogenation Tunnel has been considered in this RA document.

5 Participants

Name	Designation/ Department	Signature/ Date

6 Risk Management Process

A typical Risk management process consists of following steps:

- Risk Assessment:
  - Risk Identification
  - Risk Analysis
  - Risk Evaluation
- Risk Control
  - Risk Reduction
  - Risk Acceptance
- Result of Risk management processes
- Risk Review
- Risk Assessment consists of the identification of hazards and the analysis and evaluation of risks associated with exposure to those hazards.
  Risk identification is a systematic use of information to identify hazards referring to the risk question or problem description.
  Risk analysis is the estimation of the risk associated with the identified hazards. It is the qualitative or quantitative process of linking the likelihood of occurrence and severity of harm.

  Risk evaluation compares the identified and analyzed risk against given risk criteria. Risk evaluation considers the strength of evidence for all three of the fundamental questions.
  The output of a risk assessment is either a quantitative estimate of risk or a qualitative description of range of risk. In case of qualitative description the risk is expressed using descriptors such as “high”, “medium” or “low”.
- Risk control includes decision making to reduce and/ or accept risks. The purpose of risk control is to reduce the risk to an acceptable level. The amount of effort used of risk control should be proportional to the significance of the risk.
  Risk reduction focuses on processes for mitigation or avoidance of quality risk when it exceeds a specified (acceptable) level. Risk reduction might include actions taken to mitigate the severity and probability of harm.
  Risk acceptance is a decision to accept risk. Risk acceptance can be a formal decision to accept the residual risk or it can be a passive decision in which residual risks are not specified.
- The output/ result of the quality risk management process should be appropriately communicated and documented.

- Risk management should be an ongoing part of the quality management process. A mechanism to review or monitor events should be implemented.
- The output/ results of the risk management process should be reviewed to take into account new knowledge and experience.

- Risk management should be an ongoing part of the quality management process. A mechanism to review or monitor events should be implemented.
  The output/ results of the risk management process should be reviewed to take into account new Knowledge and experience.

  This document applies the risk management principles to identify the risks associated with the design, Construction and operational features of the proposed sterile formulation facility.
  The objectives of this risk assessment are to:
  • Review the design around a structured methodology
  • Identify the failure modes and associated risks
  • Check if the proposed control measures are adequate
  • Identify recommendations to obtain a more acceptable risk level if required

6.1 Identifying GMP risk

Identification of Risk associated with the equipment, is generally based on prior experience and the concerns of the participants of risk assessment document.

The risks identified are categorized as “GMP risk” or “Non-GMP risk”.

GMP is defined as “the practices which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.”

Thus, GMP covers all aspects of the manufacturing process: defined manufacturing process; validated critical manufacturing steps; suitable premises, storage, transport; qualified and trained production and quality control personnel; adequate laboratory facilities; approved written procedures and instructions; records to show all steps of defined procedures have been taken; full traceability of a product through batch records and distribution records; and systems for recall and investigation of complaints.

Thus those risks which might have a direct or indirect impact on the quality of the product are classified as “GMP risk”. Also, those risks which might result in regulatory guidelines non-compliance are also classified as “GMP risk”.
For example: The Hygiene level of the manufacturing areas has a direct impact on the quality of the
Product. Thus, it is classified as GMP risk.
The “Non GMP” risks include risks related to EHS, operational and other non-critical hazards.

Following types of risks are mainly identified during risk assessment process:

- Risk related to hygiene level of the manufacturing and supporting areas
- Risks related to appropriate utilities and their control (eg. power source, compressed air etc.)
- Risks related to calibration/ preventive maintenance
- Risks related to protection the environment and health & safety of personnel.

- Risks related to cleaning & sterilization
- Risks related to unidirectional flow of the material
- Risks related to cross contamination of the products
- Risks related to entry and exit of personnel and material.
- Risks related to all the environment features of the manufacturing areas.
- Risks related to requirement of particular rooms for different activities.
- Risks related to environment health and safety of personnel.

6.2 RISK ANALYSIS & EVALUATION

The risk analysis is performed using a qualitative basis of approach.

Qualitative analysis uses word form or descriptive scales to describe the magnitude of potential consequences/ impact and the likelihood that those consequences will occur.
The qualitative measures of likelihood includes descriptors like “Unlikely”, “Possible” and “Likely”, whereas the qualitative measures of consequence/ impact includes descriptors like “Minor”, “Moderate” and “Major”.

Qualitative measures of likelihood

Level	Descriptor	Example detail description
1	Unlikely	May occur at some time
2	Possible	Might occur at some time
3	Likely	Will probably occur in most circumstances

Qualitative measures of consequence/ impact

Level	Descriptor	Example detail description
1	Minor	• No impact on the product quality or outcome of the equipment. • Features required for easing equipment operation.
2	Moderate	• No direct impact on product quality/ outcome of equipment. However may indirectly affect the product quality. • Minor effect on personnel health • Used in the initial stage of operation, however it may affect the final output but those are not used for final release of output. • Effect on environment such as clean room.
3	Major	• Features having direct impact on product quality/ outcome of equipment like contact parts MOC, Surface finish, Control system, Process air quality etc. • Failure could lead to regulatory non-compliance. • Loss/ damage to equipment or its critical sub-components • Critical instruments not calibrated or not of desired range or accuracy. • Proper supporting documentation not provided. • Major effect on personnel health

Based on the above parameters of likelihood and consequence a qualitative risk analysis matrix is prepared to identify the overall Level of Risk, as mentioned in table below.

Qualitative risk analysis matrix – level of risk

Likelihood	Consequences/ Impact		
	1 – Minor	2 – Moderate	3 – Major
1 (Unlikely)	Low	Medium	High
2 (Possible)	Low	Medium	High
3 (Likely)	Medium	High	High

The final Risk level shall thus be described using descriptors such as “Low”, “Medium” & “High”, where each descriptor implies the following meaning:

Low – Risk can be accepted or ignored. These do not affect the final quality of the equipment/ system and it can be managed by routine procedures and are unlikely to need specific application of resources.

Medium – Risk required ongoing monitoring and review, to ensure level of risk does not increase. Otherwise managed by routine procedures.

High – Action plans must be developed, with clear assignments of individual responsibilities and timeframes.

7 Risk Assessment

In the following section a table is produced for the risk assessment. The significance or instruction for each column is described in the following paragraph.

Column 1 : **Serial number** of the Risk assessment item

Column 2 : **Process step/ Component**: Identify the process step or component associated with the risk.

Column 3 : **Risks:** Identify the type of risk associated with the process or procedure

Column 4 : Verify that whether risk have **GMP impact** in terms of Yes/ No.

Column 5 : **Justification:** Provide justification for declaring both Yes/ No for GMP impact in column 4.

Column 6 : For the risk **other than of GMP impact**, write that what is/ are the type of risks e.g. EHS, operational, etc.

Column 7 : **Justification:** Provide justification for considering the risk.

Column 8 : **Risk level:** Determine the risk level as High, Medium or low based on the impact.

Column 9 : **Existing Risk Control:** It is further divided into the following three sections:

Column 9a : **Mitigation Method:** Write the risk mitigation strategy as considered in the design.

Column 9b : **Residual risk level:** After the risk mitigation what is the residual risk level, whether it is Acceptable, Low or Medium.

Column 9c : **Test document:** Write the test point where the risk mitigation strategy will be verified.

Column 10 : **Proposed Additional Risk control measure:** Write the additional risk control measures which needs to be taken in case the existing risk control measures are insufficient to bring the residual risk level to low

Column 11 : **Revised Residual Risk level:** After the additional risk mitigation what is the residual risk level i.e. Low, Medium or High

Column 12 : **Mitigation Proposal:** Write the reference document where the additional risk mitigation strategy shall be verified i.e. reference number of CAPA/ Change Control, any new SOP or IQ, OQ or PQ addendum

Column 13 : **Status of RA**: Mention the status of RA whether it is open or closed

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PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ASSESSMENT FOR AMPOULE DEPYROGENATION TUNNEL

S. No. (1)	Process steps/ Component (2)	Risk (3)	GMP Risk Yes/ No	Justification	Other Risk type	Justification	Risk Level	Existing Risk Control			Proposed Additional Risk control measure (Mandatory for risk having Residual Risk Level as Medium or high)	Revised Residual Risk level	Mitigation Proposal (Mention either CAPA/ Change Control reference number, SOP, IQ, OQ or PQ)	Status of RA
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Input & Charging														
1.	Ampoule size	Equipment not suitable for different size of Ampoules	No	NA	Operational	Different Ampoule sizes may not be processed with same equipment.	Medium	Equipment is suitable for processing of different sizes of Ampoules.	Low	DQ	Verification shall be performed at the time of qualification activities	Low	OQ	
2.	Transport of Ampoules	▪ Ampoules incorrect motion on the transport belt. ▪ Infeed guide to tunnel not properly aligned with Ampoule Washing machine.	Yes	Ampoule jamming, Ampoule rupture, Ampoule cosmetic damage may take place.	No	NA	High	The transport belt is designed in such a way to avoid Ampoules from getting stuck.	Low	DQ	▪ 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 Ampoule washing machine out feed.	Low	OQ	

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3.	Transport of Ampoules	Abrasion of Ampoules due to attrition with the conveyor side walls.	Yes	Damage to Ampoules	No	NA	High	The SS (wire-mesh) conveyor belt has lateral guides which will avoid the Ampoules sliding along the tunnel walls.	Medium	DQ	▪ 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	Low	IQ & OQ	
4.	Transport of Ampoules	No Ampoules at infeed of tunnel	Yes	Tunnel may run without any Ampoules. Downstream equipment functioning may be hampered.	No	NA	High	Sensor is installed at tunnel infeed for detecting minimum load of Ampoules, along with alarm provision.	Medium	DQ	The tunnel conveyor should stop in case of minimum load at infeed.	Low	IQ & OQ	
5.	Transport of Ampoules	High/ low transport belt speed	Yes	Improper depyrogenation; damage to Ampoules	No	NA	High	Suitable instrumentation is provided to detect belt speed and position.	Medium	DQ	The control system shall have suitable mechanism to ensure desirable speed is maintained, against set value with feedback of actual speed.	Low	IQ & OQ	

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6.	Transport of Ampoules	Frequent stopping of tunnel due to no Ampoules at infeed.	Yes	Depyrogenation process and downstream equipment functioning shall be hampered.	No	NA	High	NA	High	NA	Speed synchronization between Ampoule washing machine and tunnel shall be carried out and proper connectivity should be established and qualified.	Low	OQ	
7.	Transport of Ampoules	Un-dried Ampoules enter the heating zone of tunnel directly.	Yes	Ampoules with moisture when exposed to very high temperature may break.	No	NA	High	▪ A drying zone is provided in the tunnel before heating zone. ▪ Ampoules from washing machine first enter the drying zone of tunnel, which is heated to around >50˚C to remove any residual moisture in Ampoules through exhaust system.	Low	DQ	Functionality shall be verified during execution of qualification studies	Low	IQ & OQ	
Process														

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8.	Air Supply (Drying, Depyrogenation & Cooling zone)	Inadequate air quality	Yes	Particle laden air may enter chamber and lead to Ampoule contamination.	No	NA	High	▪ Supply of filtered air through pre-filter and HEPA filter (H13 for depyrogenation zone and H14 for drying & cooling zone. ▪ Provision for installing particle monitoring iso-kinetic probe at cooling zone. ▪ Provision for monitoring non-viable particle count in all 3 zones.	Low	DQ	Monitoring of the nonviable particle concentration in tunnel during qualification.	Low	IQ & OQ	
9.	Air Supply (Drying, Depyrogenation & Cooling zone)	Choking/ Leakage in HEPA filter	Yes	▪ Non-uniform air distribution leading to improper depyrogenation. ▪ Contamination of Ampoules due to particle laden air.	No	NA	High	▪ Pre-filter has been installed at the upstream of HEPA filter to prevent direct load of particles on HEPA filter. ▪ Differential pressure transmitters/ switches is provided for monitoring differential pressure across HEPA filter in all 3 zones along with alarm provision in case of high or low DP.	Medium	DQ	▪ Integrity test of HEPA filters shall be performed during qualification. ▪ Integrity testing shall also be performed at regular intervals as per SOP.	Low	IQ & OQ	

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10.	Air Supply (Drying, Depyrogenation & Cooling zone)	HEPA filter integrity cannot be performed.	Yes	Integrity checking is a GMP requirement.	No	NA	High	▪ Provision for injecting and monitoring PAO at the time of integrity testing of the filters has been provided. ▪ Provision of downstream monitoring of HEPA filter is also be possible.	Low	DQ	Functionality shall be verified during execution of qualification studies	Low	IQ & OQ	
11.	Air Supply (Drying & Cooling zone)	Choking/ Damage of Pre-filter	No	HEPA filter is present in the downstream	Operational	Particulate matter load directly on the HEPA filter, may lead to frequent replacement of HEPA filter.	Medium	Differential pressure Transmitter/ switch is provided for indicating choking or leakage of pre-filter (of all 3 zones) with alarm provision in case of high or low DP.	Low	DQ	Pre-filters shall also be cleaned regularly as per SOP.	Low	IQ, OQ & SOP	
12.	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 Ampoules	No	NA	High	▪ High temperature resistant (>350°C) H13 grade HEPA filters is provided for depyrogenation zone. ▪ For drying & cooling zone, H14 filter with resistance up to 200°C is provided.	Low	DQ	Heater ON/ OFF action shall be interlocked with the operation of blowers to safeguard HEPA filters.	Low	IQ & OQ	
13.	Air Supply (Drying, Depyrogenation & Cooling zone)	Non-unidirectional air distribution	Yes	Unidirectional airflow is requirement for Grade A classification level	No	NA	High	▪ Provision of Unidirectional Air Flow System for all the 3 zones. ▪ HEPA filter is installed as terminal filter in all 3 zones.	Low	DQ	Smoke study shall be carried out during qualification to demonstrate unidirectional air flow.	Low	IQ & OQ	

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14.	Air flow	Inadequate air flow inside all 3 zones.	Yes	Improper Ampoule sterilization & depyrogenation	No	NA	High	▪ Blower capacity for all 3 zones is appropriate. ▪ Air velocity and pressure sensors are installed for each zone for monitoring and controlling velocity below HEPA filter and pressure of each zone. ▪ VFD is provided for automatic increasing or decreasing the blower motor RPM of respective zone, based on pressure sensor input of that zone.	Low	DQ	Functionality shall be verified during execution of qualification studies	Low	IQ & OQ	
15.	Air flow	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	▪ The air flow system for all depyrogenation and cooling zones is re circulatory type to ensure effective heating & cooling i.e. air is filtered through HEPA filter and is supplied from top of these zones. The exhaust air from below the conveyor is then recirculated back to the top of the HEPA filter. ▪ The air flow in drying zone is partial exhaust and partial re-circulation so as to exhaust moisture laden air and ensure proper heating.	Low	DQ	Functionality shall be verified during execution of qualification studies	Low	IQ & OQ	

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16.	Conveying	Conveyor belt speed low/ high	Yes	Improper residence time affects the validated depyrogenation cycle.	No	NA	High	▪ Automatic controlling of conveyor speed through variable frequency drive. ▪ Continuous online recording and printing of conveyor speed, time and temperature..	Low	DQ	Verification of accuracy of conveyor speed during qualification	Low	OQ	
17.	Ampoule Transport	Internal or outfeed gates opening low.	Yes	Depyrogenation of different sizes of Ampoules not possible.	No	NA	High	The control system is able to adjust the height of the gates as per different Ampoule sizes.	Low	DQ	Functionality shall be verified during execution of qualification studies	Low	OQ	
18.	Ampoule Transport	Internal or outfeed gates openings too wide; No control on gate position	Yes	Inadequate temperature distribution inside tunnel zones.	No	NA	High	▪ Suitable instrumentation is provided to detect gate position. ▪ Sensors are installed to detect gates open or closed status. ▪ Gates opening is adjusted automatically through control system as per requirement.	Low	DQ	Alarm shall be provided in case of malfunction of gates or sensor faulty	Low	IQ & OQ	
19.	Exhaust	Air extraction flow too high; Exhaust air too hot.	Yes	Inadequate temperature distribution inside depyrogenation zone.	No	NA	High	Temperature sensors is provided for monitoring temperature inside the depyrogenation zone as well as in the supply and exhaust line along with alarm provision in case of too high or low temperature.	Medium	DQ	Suitable system shall be provided to regulate the exhaust air flow from the depyrogenation chamber so as to ensure effective heating of Ampoules.	Low	IQ & OQ	

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20.	Ampoule transport	Differential pressure between different zones cannot be maintained	Yes	▪ Inadequate temperature distribution inside tunnel ▪ May lead to contamination of sterile, depyrogenated Ampoules.	No	NA	High	▪ A proper pressure system is designed i.e. design pressure of each zone will ensure desired flow pattern in such a way that depyrogenating zone will be positive with respect to adjacent zones. ▪ Automatic gates are installed between each zone and at infeed and out feed for maintaining required pressure of each zone. .	Medium	DQ	▪ 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	Low	IQ & OQ	
21.	Heating	Low temperature inside the drying zone.	Yes	Inadequate Ampoules drying	No	NA	High	▪ Temperature sensor is installed inside the drying zone with alarm provision in case of low temperature. ▪ Heating provision is provided in the drying zone for heating of Ampoules to effectively remove residual moisture.	Medium	DQ	▪ 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.	Low	IQ, OQ & SOP	

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22.	Heating	High temperature inside the depyrogenation zone	Yes	Ampoule damage or rupture; HEPA filter burning	No	NA	High	▪ Temperature sensor is installed inside the depyrogenation zone with alarm provision in case of high temperature. ▪ Heating system will off in case of high temperature.	Low	DQ	Frequent checking of the wear and tear of the heating element as per preventive maintenance SOP.	Low	IQ, OQ & SOP	
23.	Heating	Low temperature inside the depyrogenation zone.	Yes	Inadequate Ampoules sterilization & depyrogenation.	No	NA	High	▪ Temperature sensor is installed inside the depyrogenation zone with alarm provision in case of low temperature and stoppage of conveyor. ▪ Heating elements of sufficient capacity is considered while designing.	Low	DQ	▪ Alarm provision in case heating system faulty. ▪ Routine maintenance of heating system shall be carried out as per preventive maintenance SOP	Low	IQ, OQ & SOP	
24.	Heating	Heat distribution profile (ventilation) not proper.	Yes	Inhomogeneous distribution of air, depyrogenation not reproducible	No	NA	High	▪ Sensors for temperature monitoring are provided in all 3 zones along with alarm provision in case of high/ low temperature. ▪ Design of the equipment ensures proper heat distribution profile in all 3 zones.	Medium	DQ	▪ Temperature mapping shall be performed during qualification. ▪ Tunnel should be capable to reduce the endotoxin load in the Ampoule by more than 3 log.	Low	IQ, OQ & PQ	

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25.	Cooling of Ampoules	Ampoules temperature at outfeed of cooling zone too high	Yes	Chances of Ampoule damage due to rapid change in temperature.	No	NA	High	Air based cooling is provided in cooling zone.	Low	DQ	Conveyor belt should stop in case set cooling temperature is not achieved.	Low	IQ & OQ	
26.	Compressed air	Insufficient/ No pressure	Yes	Equipment operation will be disturbed	No	NA	High	Pressure gauge/ Pressure switch is provided at compressed air inlet to monitor & control compressed air pressure along with alarm provision in case of low pressure.	Low	DQ	Functionality shall be verified during execution of qualification studies	Low	IQ & OQ	
Discharge														
27.	Output from Tunnel	Output of depyrogenation tunnel is not synchronized with filling machine.	No	No impact on depyrogenation process	Operational	Proper flow of the Ampoules gets disturbed.	Medium	NA	Medium	NA	Co-ordination between each of these modules shall be carried-out and proper connectivity shall be established and qualified.	Low	OQ	
28.	Out feed	Maximum accumulation at out feed buffer rotary plate.	No	No impact on depyrogenation process	Operational	Ampoules may fall off due to high accumulation at out feed	High	▪ Out feed occupancy sensor is provided to detect maximum accumulation at buffer rotary plate. ▪ Full occupancy at the out feed rotary plate of the tunnel will be interlinked with the tunnel conveyor.	Low	DQ	Tunnel conveyor shall stop in case out feed is full.	Low	IQ & OQ	

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Equipment Construction- Internal Surface														
29.	Metallic components in direct contact with Ampoules	The material may not be suitable; may contaminate Ampoules during sterilization	Yes	MOC not resistant - Interaction with media possible	No	NA	High	▪ Metallic critical contact surfaces are constructed of 316 grade stainless steel or better. • Supporting structure and non-contact parts are made up of SS 304 or better.	Low	DQ	The suitability of the materials shall be proven by certificate/ manufacturers declarations	Low	IQ	
30.	Polymeric materials	Polymeric materials are not compatible and are not replaceable	Yes	Shall lead to contamination of Ampoules.	No	NA	High	Gaskets and O-rings coming in direct/ indirect contact surfaces is made up of food grade polymeric materials only and shall be high temperature and pressure resistant.	Low	DQ	• Food grade polymeric material certificate/ declaration have to be provided by vendor • The easy change of gaskets should be possible.	Low	IQ	
31.	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	All welds are ground finished and properly passivated.	Low	DQ	Weld reports/ certificate/ declaration have to be provided by vendor.	Low	IQ	

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32.	Metallic contact parts.	Internal surface finishing insufficient	Yes	May lead to improper cleaning of the surface which will lead to microbial growth hence Ampoule contamination	No	NA	High	Internal surface is constructed of 316 grade stainless steel or better.	Low	DQ	The suitability of the materials & roughness, Ra ≤ 0.8 µm shall be proven by certificate/ manufacturers declarations.	Low	IQ	
33.	Insulation	Material not suitable	Yes	Leads to contamination	No	NA	High	Insulation material is fibrous and covered with completed welded SS304 or better cladding.	Low	DQ	Functionality shall be verified during execution of qualification studies	Low	IQ & OQ	
Equipment Construction- External Surface														
34.	Surface	External surface of equipment is not suitable	Yes	May lead to the clean room contamination	No	NA	Medium	Supporting structures and frames installed inside clean rooms are made up of SS 304 or better grade stainless steel.	Low	DQ	The suitability of the materials shall be proven by certificate/ manufacturers declarations.	Low	IQ	
35.	Finishing	External finish of equipment is not proper.	Yes	May lead to the microbial growth	No	NA	Medium	NA	Medium	NA	External surface should be free from sharp edges, corners, crevices etc., all metallic external surface shall be matt or mirror finished.	Low	IQ	

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Cleaning														
36.	Cleaning	Difficult cleaning	Yes	Accumulation of particles, contamination of clean room possible	No	NA	High	All bolts, nuts on the exterior part of equipment is made as per clean room design, for e.g. provided with dome nuts, etc.	Medium	DQ	• 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).	Low	IQ	
37.	Labeling of components	Labeling of components/ media inappropriate	Yes	Prerequisite for qualification &maintenance	No	NA	Medium	Unique identity number/ flow direction is provided on components/ media, operator panel, etc. (e.g. according to P&ID).	Low	DQ	• Labels affixed on the equipment should be heat resistant. • All labelling shall be done in English language and according to P&ID	Low	IQ	
PLC/ Control System														

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38.	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 System is PLC based and fully automatic.	Low	DQ	The equipment shall control & detect failure mode automatically.	Low	IQ & OQ	
39.	Man-machine Interface	Process / process status not visible for operating personnel.	Yes	Operating personnel must have knowledge on the process status	No	NA	High	MMI is provided with adequate display and clean room suitable key board for operation and entering process parameters.	Low	DQ	NA	Low	IQ	
40.	Man-machine Interface	Display language not identified.	Yes	Pre-requisite for the GMP compliant operation	No	NA	High	.NA	High	NA	The language on the display of MMI shall be English language	Low	OQ	
41.	Man-machine Interface	Monitoring of GMP relevant data not possible	Yes	Basic GMP requirement	No	NA	High	Printout facility is available with fade proof prints.	Medium	DQ	Monitoring of GMP relevant data should be possible	Low	OQ	
42.	Man-machine Interface	Recorder failure	Yes	Basic GMP requirement; Critical process parameters & batch report might not be saved and printed.	No	NA	High	Data backup for process data is provided (electronic recording, 21 CFR part 11 compliant).	Medium	DQ	• 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.	Low	OQ, PLC Validation & SOP	

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43.	PLC/ Control system	Control system does not detect failures and generate alarms	Yes	Process optimization and validation is not possible	No	NA	High	Alarm is provided in case of any critical instrument/ sensor not working properly, loss of communication or broken wire.	Medium	DQ	• 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.	Low	OQ	
44.	PLC / Control system	Status parameters not clear	Yes	Process for the particular product at particular stage can't be regulated easily.	No	NA	High	• Status parameters are remaining displayed at each process stage. • Alarm is visualized along with the fault displayed.	Low	DQ	Verification shall be performed at the time of qualification activities.	Low	OQ	

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ASSESSMENT FOR AMPOULE DEPYROGENATION TUNNEL

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45.	PLC / Control system	Power failure/ emergency stop	Yes	Process out of specification	Safety	Unsafe if start automatically on restoration of power	High	• Alarm message; • On power failure equipment comes to rest to protect operator, equipment itself & the articles. • Machine is not start automatically without operator intervention after incident.	Medium	DQ	• SOP for "Operation and Maintenance of Ampoule 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.	Low	IQ, OQ & SOP	
46.	PLC / Control system	Malfunction of control system	Yes	Correct function of control system is a basic requirement for GMP-compliant operation	No	NA	High	The equipment contains all necessary protection devices to ensure that the equipment and article remain in safe condition.	Medium	DQ	• Input/ Output test implementation during qualification activities • Control system software backup should be provided by the vendor.	Low	OQ	

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47.	Accessibility to PLC	Parameter settings not identified universally	Yes	Basic GMP requirement	No	NA	High	NA	High	DQ	Parameters settings shall be in numeric only.	Low	OQ	
48.	PLC / Control system	Time measurement works incorrect	Yes	Process cannot be carried out using validated parameters.	No	NA	High	NA	High	NA	• Time verification of the system clock shall be performed at frequent intervals as per SOP. • PLC Clock verification shall be performed during qualification.	Low	OQ & SOP	
49.	PLC / Control system	No protection of PLC against manipulation & changes.	Yes	Basic GMP requirement.	No	NA	High	Minimum 3 level password protections is provided for the system. ➢ Level 1: Operator ➢ Level 2: Supervisor ➢ Level 3: Admin/ Manager	Low	DQ	• All users shall be provided with unique passwords. • System shall allow only authorized users to access system and change parameters.	Low	OQ	

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50.	PLC/ Control System	Wrong programs (Not appropriate for the designated process)	Yes	Process out of specification	No	NA	High	PLC/System is equipped with different number of programs, dedicated for different container sizes.	Low	DQ	• Verification of correct program, set values during qualification. • List of all process relevant parameters including related, programmed limits shall be described in SOP.	Low	OQ, PQ & SOP	
Measuring Instruments														
51.	Measuring Instruments	Measuring instruments not suitable	Yes	Improper measurements	No	NA	High	• Measuring Instruments installed have suitable measuring range. • Measuring Instruments have appropriate accuracy.	Low	DQ	Operational range of Measuring Instruments > equipment's working range.	Low	IQ & OQ	
52.	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	• Measuring instruments are calibrated, traceable to national or international standards. • Re-calibration of instruments is possible.	Low	DQ	Test certificate shall be verified during execution of qualification studies	Low	IQ & OQ	

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53.	GMP relevant measurement instruments	Instruments cannot be dismounted	Yes	Defective instruments must be dismounted for exchange and calibration	No	NA	High	NA	Low	NA	• Mounting of instruments should give the possibility for dismounting and replacement • Constructional solution: easy access for re-calibration activities shall be provided.	Low	IQ	
Maintenance														
54.	Maintenance	Malfunctions due to worn parts	Yes	Basic GMP requirement	No	NA	High	Preventive maintenance procedure is provided by the vendor.	Low	DQ	• 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.	Low	IQ & SOP	

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55.	Motors	Motors failure	Yes	Depyrogenation process may be affected	No	NA	High	Alarm provision in case of motor failure or overload.	Low	DQ	Preventive maintenance of motors shall be carried out at regular intervals as per SOP.	Low	OQ & SOP	
Environment & Safety														
56.	Electrical system	• 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	NA	Medium	NA	• 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.	Low	IQ	
57.	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	Emergency stop shall is installed on accessible area, along with alarm provision.	Low	DQ	Verification shall be performed at the time of qualification activities.	Low	IQ & OQ	
58.	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	Noise level is below 80 db at a distance of 1 m from the equipment.	Low	DQ	Verification shall be performed at the time of qualification activities.	Low	OQ	

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59.	Moving & electrical parts	Moving & electrical parts are not covered.	No	Does not have any impact on quality of the product	EHS	Operator safety	Medium	All moving & electrical parts shall be covered properly.	Low	DQ	Verification shall be performed at the time of qualification activities	Low	IQ & OQ	
60.	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	▪ Proper insulation is provided such that external surface temperature will not be more than 45 ºC. ▪ SS 304 cladding is provided above insulation.	Low	DQ	▪ Warning sticker should be provided on hot surfaces. ▪ Insulation material should be resin bounded Glass wool / Rock wool.	Low	IQ & OQ	
61.	Heating	Excess heating & excess pressure	No	No impact on process	EHS	Environmental & operator safety hazards.	Medium	Elevated temperature & pressure above set limit will lead to an alarm.	Low	DQ	Temperature & Pressure limit for the resistance of the equipment should be defined.	Low	OQ	
62.	Classification Level	Cooling zone does not maintain Grade A when tunnel is off at night and during holidays	Yes	Contamination of Ampoules in the cooling zone	No	NA	High	Night mode operation is provided i.e. at night or during holidays only blower will be ON, to have laminar air flow barrier at higher pressure with respect to washing area.	Low	DQ	Verification shall be performed at the time of qualification activities	Low	IQ & OQ	

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63.	Equipment access doors	Service access doors (for maintenance) may be opened during process.	Yes	▪ If access doors are opened, the clean room temperature and RH conditions may deviate. ▪ Chances of particulate contamination of Ampoules	EHS	Operator safety risk, as moving parts shall be exposed.	High	Security switches/ sensors are provided at the service access doors; with interlock feature with the operation of machine i.e. machine stops immediately if any of the access doors is opened.	Low	DQ	Alarm provision shall also be provided for the same.	Low	IQ & OQ	
Documentation														
64.	User	Faulty operation & maintenance	Yes	SOPs are basic GMP-requirement	No	NA	High	NA	High	NA	▪ 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, trouble shooting & maintenance related activities.	Low	OQ & SOP	

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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	Hig h	NA	Low	DQ	• 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.	Low	OQ & SOP	
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	Hig h	System is not start without password.	Low	DQ	Key switch should be provided for operation of the system	Low	IQ & OQ	

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67.	Vendor	Technical documentation from vendor not adequate	Yes	Adequate technical documentation is basic GMP requirement	No	NA	High	Following documents is provided by vendor (in English): ▪ DQ/ FS, IQ and OQ documents ▪ Welding certificates/ declaration along with welder qualification certificate. ▪ Material certificates & surface finish reports ▪ O&M manual ▪ Calibration certificates of all instruments ▪ Software backup ▪ Parts list (sufficient details - part no., supplier, type etc.) ▪ Drawings (P&ID, GA, Power wiring etc.). ▪ Certificates of bought out components. ▪ Filter certificates	Low	DQ	Verification of documents shall be performed at the time of qualification activities	Low	IQ	

8 Summary & Conclusion

- The Risk Assessment was performed to establish the design parameters of the equipment so as to meet the desired performance of the equipment i.e. Ampoule Depyrogenation Tunnel.
- The critical risks pertained to GMP and other than GMP, were analyzed with justification and mitigation procedures.
- For each recognized GMP-risk and other than GMP risks, necessary measures are defined. Organizational measures, like SOPs, are also possible measures for special GMP-risks. The availability of these SOPs will be checked during the performance of the OQ.
- The risks where conceptual procedures shall be employed, standard operating procedures (SOPs), Preventive maintenance schedules, Certificates and related documents indicated as mitigation procedures shall be ensured at respective test points

*"It is concluded that the **Risk Assessment** performed for the equipment will prevent the risk of failures of critical parameters during, design commissioning, installation, operation and performance of the equipment".*

9 Abbreviations

EU-GMP	:	European – Good Manufacturing Practice
EHS	:	Environment Health Safety
GMP	:	Good Manufacturing Practices
HEPA	:	High Efficiency Particulate Air
DP	:	Differential Pressure
RA	:	Risk Assessment
VFD	:	Variable Frequency Drive
PAO	:	Poly-alpha olefin
RPM	:	Revolutions per minute
SOP	:	Standard Operating Procedure
Ra	:	Roughness Average
SS	:	Stainless Steel
P&ID	:	Process/ Piping & Instrumentation Diagram
PLC	:	Programmable Logic Controller
MMI	:	Man Machine Interface
CFR	:	Code of Federal Regulations
UPS	:	Uninterrupted Power Supply
CE	:	Conformité Européene
db	:	Decibel
DQ	:	Design Qualification
FS	:	Functional Specification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PQ	:	Performance Qualification
O&M	:	Operation and Maintenance
GA	:	General Arrangement
IPSI	:	Integrated Project Services International, New Delhi

10 Revision History

Date	Revision	Reason for Revision
	00	New Document