Risk Assessment Document

For

Vial Sealing Machine

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RISK ASSESSMENT FOR VIAL SEALING MACHINE

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 Vial Sealing Machine which shall consist of the following main components:

The Vial Sealing machine shall be an automatic machine, with preferably 8-12 heads. The machine shall be used to seal the duly stoppered vial filled with product in either lyophilized or in liquid form. The machine shall be suitable to handle different sizes of product filled vials as per requirement.

Sealing machine shall be used for crimping/sealing of the vials. Stoppered vials from the automatic unloading system of lyophilizer or from Vial Filling & Stoppering machine shall be conveyed to the infeed turntable of the sealing machine. Thereafter, conveyor belt shall feed the vials in to the star wheel & star wheel shall feed the stoppered vials to the sealing turret.

The sealing turret shall consist of 8-12 sealing heads which shall be identical. During transfer, the vials shall collect a seal from the end of the seal feed chute and imparts it in a proper orientation for the sealing. Sealing head shall skirt, spin & seals the seal on to the neck of the vials.

The complete Vial sealing machine along with the transfer system at the upstream of equipment shall be installed under oRABs system with Grade A classification.

The machine shall consist mainly of the following main components:

- Infeed turntable
- Vial Infeed belt

- Screw Feeder
- Vial infeed star wheel
- Sealing rotor/ turret
- Discharge star wheel
- Discharge conveyor
- Out feed turntable

Most of the possible risk concerning the handling/ operation of the Vial Sealing Machine 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.

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  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 of 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

Level	Descriptor	Example detail description
		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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RISK ASSESSMENT FOR VIAL SEALING MACHINE

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Input & Charging														
1.	Vial size	Equipment is not suitable for sealing of different size of vials	No	No impact on product quality.	Operational	Different vial sizes may not be processed with same equipment.	Medium	Equipment is suitable for sealing of different sizes of vials by changing format (change) parts.	Low	DQ	▪ Change parts for different vial size shall be provided by vendor, along with the equipment. ▪ Functionality shall be verified during execution of qualification activities.	Low	IQ & OQ	
2.	Feeding of vials	Feed rate cannot be controlled; inadequate capacity of the equipment	Yes	▪ Upstream equipment functioning will be disturbed. ▪ Sealing may take longer time.	Operational & Safety	▪ Uncontrolled feeding of product will lead to frequent breakdown and loss of productivity. ▪ Broken vials may be safety risk for operators.	Medium	▪ Feed rate of vials to sealing machine could be controlled through control system. ▪ The transfer of seals for sealing is also controlled with control of vibration intensity by control system.	Low	DQ	The equipment capacity should be sufficient to support upstream equipment capacity as well as production requirement	Low	OQ & PQ	

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3.	Transfer of vials from filling to sealing station.	Product filled vials travel through unclean (unclassified) environment	Yes	Particle contamination of vial; microbiological contamination possible	No	NA	High	The transfer of vials is performed under LAF (Grade A).	Low	DQ	Classification level shall be verified and qualified during qualification.	Low	IQ & OQ	
4.	Transfer of vials	Overturned/ fallen vials on the infeed conveyor belt.	Yes	Vial jamming, vial damage or rupture may take place	No	NA	High	▪ Screw feeder (or suitable mechanism) is provided at the infeed guide to prevent falling of vials. Overturn/ fallen vials on infeed guide shall be detected and will result in jamming and machine stoppage along with alarm provision. ▪ Speed of the transfer conveyor is controlled by control system through VFD, to stop jerk & allow smooth flow, thereby preventing vials from overturning/ falling.	Low	DQ	▪ Vial transfer system shall be designed in a way to prevent falling of vials. ▪ Functionality shall be verified during execution of qualification activities.	Low	OQ	

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5.	Transfer of Vials	Vials minimum load on the infeed conveyor.	Yes	No vials supplied to the vial sealing machine; improper operation of sealing machine.	No	NA	High	Vials minimum load detection sensor is provided at sealing machine inlet line to detect the low accumulation vials, along with alarm provision.	Low	DQ	Machine shall stop and goes into standby mode in case of low vials at infeed.	Low	IQ & OQ	
Process														
6.	Transfer of Vials	No Stopper on vials	Yes	Improper sealing leading to product contamination	No	NA	High	▪ Sensor is provided at the inlet line of machine to check the presence of stopper on vials. ▪ Un-stoppered vials will be rejected through a separate guide to the rejection system.	Medium	DQ	Continuous vials (value settable through control system) with missing stopper shall lead to machine stoppage along with alarm.	Low	IQ & OQ	
7.	Transfer of Vials	Raised stopper on vials	Yes	Improper sealing leading to product contamination	No	NA	High	▪ Sensor is provided at the inlet line of machine to check the height of stopper on vials. ▪ Raised stoppered vials will be rejected through a separate guide to the rejection system.	Medium	DQ	Continuous vials (value settable through control system) with raised stopper shall lead to machine stoppage along with alarm.	Low	IQ & OQ	

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8.	Transfer of Vials	Sensor for no stopper & raised stopper faulty or defective.	Yes	Machine may not work properly; Anomalies may occur.	No	NA	High	The control system/ PLC will continuously check the proper functioning of these sensors.	Low	DQ	If sensors are not working, the control system should stop the machine along with alarm.	Low	OQ	
9.	Sealing	Vial not present on sealing station	Yes	Machine may not work properly; Anomalies may occur.	No	NA	High	▪ Sensor shall be installed at the infeed conveyor to check and assure the presence of vials. ▪ No vial-No sealing function shall be provided in the system.	Low	DQ	Functionality shall be verified during execution of qualification activities.	Low	IQ & OQ	
10.	Sealing	No seals on vials before sealing	Yes	Improper sealing leading to product contamination	No	NA	High	▪ Sensor is provided at the inlet line of machine before the sealing station to check the presence of seal on vials. ▪ Vials without seals will be rejected through a separate guide to the rejection system.	Low	DQ	Continuous vials (value settable through control system) without seals before sealing station shall lead to machine stoppage along with alarm.	Low	IQ & OQ	
11.	Sealing	Sensor for no seal on vials is faulty or defective	Yes	Machine may not work properly; Anomalies may occur.	No	NA	High	The control system/ PLC will continuously check the proper functioning of sensor.	Low	DQ	If sensor is not working, the control system should stop the machine along with alarm.	Low	OQ	

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12.	Sealing	Improperly sealed vials or vials with no seal get discharged to the downstream equipment.	Yes	Vials with improper sealing/ no seal may be processed further.	No	NA	High	▪ Sensor is provided at sealing machine outlet to sense improperly sealed vials or vials with no seals, after sealing station. ▪ Vials without seals or improperly sealed vials will bypass to the different route and rejected.	Low	DQ	Functionality shall be verified during execution of qualification activities.	Low	IQ & OQ	
13.	Sealing	Sensor for improperly sealed vials are faulty or defective	Yes	Machine may not work properly; Anomalies may occur.	No	NA	High	The control system/ PLC continuously check the proper functioning of sensors.	Low	DQ	If sensors are not working, the control system should stop the machine along with alarm.	Low	OQ	
14.	Sealing	Sealing speed could not be regulated and controlled.	Yes	Sealing system incorrect performance. Variation in output.	No	NA	High	Counter is placed at infeed and out feed to count number of sealed and rejected vials.	Low	DQ	The equipment control system shall be suitable to adjust & maintain the rate of sealing (number of vials/ minute).	Low	IQ & OQ	

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15.	Sealing	Sealing carried out under unclean environment.	Yes	Unidirectional airflow is GMP requirement till for sealing of aseptically filled products.	No	NA	High	Unidirectional Air Flow system (Grade A) is provided over complete sealing machine.	Low	DQ	Classification level shall be verified and qualified during qualification	Low	IQ & OQ	
16.	Sealing	Incorrect presentation of seals at sealing station	Yes	Incorrect sealing of vials	No	NA	High	Provision of vibrating bowl feeder accompanied with feeding chute for correct presentation of seals at sealing station.	Low	DQ	Functionality shall be verified during execution of qualification activities.	Low	IQ & OQ	
17.	Sealing	No seals in bowl & hopper	Yes	Vials will not be sealed	No	NA	High	Sensor is provided to monitor level of seals in vibratory bowl and hopper, along with alarm provision.	Low	DQ	Functionality shall be verified during execution of qualification activities.	Low	IQ & OQ	
18.	Sealing	Low level of seals at chute/ track	Yes	Vials will not be sealed	No	NA	High	▪ Sensor is provided on feeding chute for detecting minimum level of seals. ▪ Alarm will generate in case of low level, along with machine stoppage.	Low	DQ	Functionality shall be verified during execution of qualification activities.	Low	IQ & OQ	

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19.	Sealing	Low vacuum	Yes	Sealing activity shall be impacted.	No	NA	High	▪ Vacuum pump is provided for the sealing machine. ▪ Pressure switch/ regulator is provided on vacuum supply line ▪ Low vacuum will alarmed leading to machine stoppage.	Low	DQ	Functionality shall be verified during execution of qualification activities.	Low	IQ & OQ	
20.	Sealing	Sealing station height not adjustable.	Yes	Improper sealing for different size of vials.	No	NA	High	Control system has provision for adjusting the sealing level height automatically as per vial size.	Low	DQ	Functionality shall be verified during execution of qualification activities.	Low	IQ & OQ	
21.	Utility	Inadequate or low pressure of compressed air	Yes	Process may be affected	No	NA	High	Pressure switch/ transmitter shall be installed on compressed air inlet line along with alarm provision in case of low pressure.	Low	DQ	Machine shall stop in case of insufficient pressure of the compressed air.	Low	IQ & OQ	
Discharge														

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22.	Discharge of vials	Vial incorrect motion in the outfeed star wheel; Vials get stuck in outfeed star wheel.	Yes	Vial Jamming, rupture, vial cosmetic damage may take place.	Operational	▪ Product spillage may contaminate the area. ▪ Yield Loss	High	Out feed star wheel is designed in a way to avoid vials from getting stuck.	Low	DQ	▪ The out feed star wheel movement shall be in sync with the sealing machine movement. ▪ Vial jam at out feed star wheel shall lead to machine stoppage along with alarm provision.	Low	IQ & OQ	
23.	Discharge of vials	Magazine tray unit not in place	Yes	Sealed good vials may fall; vial damage	Operational	▪ Product spillage may contaminate the area. ▪ Yield Loss	High	Magazine tray units are provided at the discharge side for collection of sealed vials.	Low	DQ	Alarm shall be provided in case magazine tray unit is not in place along with machine stoppage.	Low	IQ & OQ	
Equipment Construction- Internal Surface														
24.	Metallic components in direct contact with vials/ compressed air	The material may not be suitable; may contaminate Vials.	Yes	MOC not resistant - Interaction with media possible	No	NA	High	• Metallic critical contact surfaces is constructed of 316 grade stainless steel or better, electro polished, orbitally welded. • Supporting structure and non-contact parts shall be made up of SS 304 or better.	Low	DQ	The suitability of the materials shall be proven by certificate/ manufacturers declarations	Low	IQ	

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25.	Polymeric materials	Polymeric materials are not compatible and are not replaceable	Yes	Shall lead to contamination of Vials.	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	
26.	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 and orbital welding is to be performed, wherever possible.	Low	DQ	Weld reports/ certificate/ declaration have to be provided by vendor.	Low	IQ	
27.	Metallic contact parts.	Internal surface finishing insufficient	Yes	May lead to improper cleaning of the surface which will lead to microbial growth.	No	NA	High	Internal surface is constructed of 316 grade stainless steel or better, electro polished, orbitally welded.	Low	DQ	The suitability of the materials & roughness, Ra ≤ 0.8 µm shall be proven by certificate/ manufacturers declarations.	Low	IQ	
Equipment Construction- External Surface														

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28.	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	
29.	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	
Cleaning														
30.	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	

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31.	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														
32.	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	
33.	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 /Touch screen for operation and entering process parameters.	Low	DQ	NA	Low	IQ	
34.	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	
35.	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	

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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
								Risk Control	Residual risk level	Reference Document				
36.	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	
37.	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	
38.	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	

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39.	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 Vial Sealing machine" 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	
40.	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	
41.	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	

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42.	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	
43.	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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44.	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														
45.	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	
46.	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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47.	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														
48.	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	
49.	Star wheels & Main drive	Star wheels & main drive overload	Yes	Sealing process may be affected	No	NA	High	Alarm is provisioned in case of star wheels and main drive overload.	Low	DQ	Preventive maintenance of star wheels and motors shall be carried out at regular intervals as per SOP.	Low	OQ & SOP	

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50.	Vacuum Pump	Vacuum Pump overload	Yes	Sealing process may be affected	No	NA	High	Alarm provision is available in case of vacuum pump overload.	Low	DQ	Preventive maintenance of vacuum pump shall be carried out at regular intervals as per SOP.	Low	OQ & SOP	
51.	Change parts	Difficult maintenance & time consuming change-over	No	NA	Operational	Improper maintenance & time consuming change-over will affect the quality & productivity of the product	Medium	• Full access to the machine is provided for changing parts. • Limited number of change parts is be provided leading to efficient change-over. • Change parts for different size of vials are provided with quick-fit arrangement.	Low	DQ	The change parts should be identified by non-erasable marking.	Low	IQ & OQ	
Environment & Safety														
52.	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	

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53.	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	
54.	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 75 db at a distance of 1 m from the equipment.	Low	DQ	Verification shall be performed at the time of qualification activities.	Low	OQ	
55.	Moving & electrical parts	Moving & electrical parts are not covered.	No	Does not have any impact on quality of the product	EHS	Operator safety	Medium	The main sealing station is covered with a protective, removable acrylic covering.	Low	DQ	All moving & electrical parts shall be covered properly.	Low	IQ & OQ	
56.	LAF (over Sealing Machine & infeed conveyor)	The air flow from LAF is not uniform or is turbulent.	Yes	Turbulent or insufficient flow may lead to particulate contamination of the product inside vials.	No	NA	High	Uniform unidirectional flow will maintain from the LAF up to the working area inside oRABs.	Low	DQ	▪ A uniform air velocity of 90 fpm ± 20% shall be maintained at the working level inside oRABs. ▪ Air velocity and smoke study shall be carried out during qualification for verification of the same.	Low	IQ & OQ	

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57.	Hygiene Conditions	Non-Viable and Viable particle count monitoring not possible.	Yes	Basic GMP requirement for Grade A environment.	No	NA	High	▪ Non-viable particle count locations are provided. ▪ Equipment has arrangement for installing online particle counters.	Low	DQ	▪ Position for settle plates next to critical positions shall be provided and location shall ensure that there is no disturbance in LAF flow. Monitoring of particles (viable/ non-viable) shall be performed during qualification. ▪ Routine microbiological monitoring shall be performed as per SOP.	Low	IQ, OQ & SOP	
58.	LAF (over Sealing Machine & infeed conveyor)	LAF fails/ Stops	Yes	Contamination of product is possible if machine is in operation.	No	NA	High	Machine operation is interlocked with LAF's operation, which will be mounted on top of the entire sealing machine and its infeed conveyor.	Medium	DQ	▪ Machine shall stop in case of any LAF failure. ▪ Alarm provision shall be provided in case LAF fails/ stops.	Low	IQ & OQ	

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59.	LAF (over Sealing Machine & infeed conveyor)	HEPA Filter leakage/ Choking	Yes	In case of leakage may lead to product contamination.	No	NA	High	▪ Pre-filter is installed at the upstream of HEPA filter to prevent direct load of particles on HEPA filter ▪ Differential pressure is provided to monitor pressure across all HEPA filters of LAF.	Low	DQ	Integrity test of HEPA filters shall be performed during qualification and routinely as per SOP.	Low	IQ & OQ	
60.	LAF (over Sealing Machine & infeed conveyor)	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 switch/ gauge is provided for indicating choking or leakage of pre-filters 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	
61.	oRABs access doors	oRABs access door may be opened during process.	Yes	Chances of product contamination by direct handling of operators.	EHS	Operator safety risk	High	▪ Security switches/ sensors are provided at the access doors with interlock feature with the operation of machine i.e. machine will stop immediately if oRABs access doors are opened. ▪ Alarm provision is also provided for the same.	Low	DQ	Functionality shall be verified during execution of qualification activities.	Low	IQ & OQ	

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62.	Equipment access doors	Service access door may be opened during process.	No	No impact on process	EHS	Operator safety risk, as machine's moving parts shall be operating.	Medium	▪ Security switches/ sensors are provided at the service access doors along with interlock feature i.e. machine should stop immediately if service doors are opened. ▪ Alarm provision is also provided for the same.	Low	DQ	Functionality shall be verified during execution of qualification activities.	Low	IQ & OQ	
63.	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 activities.	Low	IQ & OQ	
Documentation														

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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	
65.	User	Operation SOP does not contain proper information and user may operate system	Yes	User may make a wrong decision.	No	NA	High	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	High	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. Vial Sealing Machine.
- 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
RA	:	Risk Assessment
SOP	:	Standard Operating Procedure
AISI	:	American Iron and Steel Institute
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
LAF	:	Laminar Air Flow
oRABs	:	Open Restricted Access Barrier System
HEPA	:	High Efficiency Particulate Air
UDAF	:	Unidirectional air flow
PAO	:	Poly Alfa Olefin
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