Risk Assessment Document
For
Ampoule Washing Machine

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RISK ASSESSMENT FOR AMPOULE WASHING 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 Ampoule Washing Machine which shall consist of the following main components:

a) Feeding tray/ platform: For manual feeding of Ampoules.
b) Transport conveyors: Ampoules from the feeding tray shall be transferred through transport conveyors to the infeed star wheel.
c) Infeed Star wheel: Ampoules are separated & elevated out of the conveyor & delivered to the revolving main star wheel.
d) Cleaning stations: Ampoules are gripped by grippers, who rotate the Ampoules by 180˚, so that opening of Ampoules are below. Ampoules are then passed through the cleaning station upside down & at the individual station the spray tubes travel in synchronization to wash the Ampoules with re-circulated water, Purified water & Fresh WFI and dry the Ampoules with compressed air.
e) Discharge star wheel: Ampoules are reversed by 180^0 & engaged in the slots of a discharge star wheel & pushed back to back to the down line machine in upright condition.

Most of the possible risk concerning the handling/ operation of the Ampoule Washing 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.

- 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.

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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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Input & Charging														
1.	Ampoule size	Equipment is not suitable for different size of Ampoules.	No	No impact on product quality	Operational	Different Ampoule sizes may not be processed with same equipment.	Medium	• Equipment is suitable for washing of different sizes of Ampoules by changing format parts. • Format parts for different Ampoule sizes are provided by vendor along with the equipment, as per requirement.	Low	DQ	Verification of functionality with different change parts shall be performed during qualification studies	Low	IQ & OQ	
2.	Transfer of Ampoules	Overturned Ampoules on the in-feed conveyor.	Yes	Ampoule jamming, Ampoule damage or rupture may take place	No	NA	High	• Conveyor is designed in a way to prevent falling of Ampoules on the transfer belt. • Speed of the conveyor shall be controlled through VFD to stop the jerk & allow smooth flow, preventing Ampoules from overturning/ falling.	Medium	DQ	Machine should stop in case overturned ampoules are detected on the infeed conveyor belt.	Low	IQ & OQ	
3.	Transfer of Ampoules	Improper positioning of Ampoules during transfer to washing station.	Yes	Inadequate washing leading to contamination	No	NA	High	The design of the system ensures that individual grippers transport the Ampoules with positive grip on Ampoule neck.	Medium	DQ	Functionality shall be checked qualification stages.	Low	IQ & OQ	

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4.	Transfer of Ampoules	Ampoules minimum load on the infeed transfer conveyor.	Yes	• No Ampoules supplied to the ampoule washing machine. • Unnecessary operation; wastage of utilities.	No	NA	High	Ampoules minimum load detection sensor is provided on the infeed guide to detect the low accumulation of Ampoules along with Alarm provision.	Medium	DQ	Machine should go into standby mode/ stop in case of low Ampoules at infeed conveyor.	Low	IQ & OQ	
Process														
5.	Washing nozzles	Incorrect insertion of nozzles into the Ampoules.	Yes	• May lead to Ampoule damage or rupture. • Inadequate Ampoule washing or drying.	No	NA	High	Nozzle system movement keeps in phase with the internal transport systems by means of mechanical cams.	Medium	DQ	Functionality shall be checked qualification stages.	Low	OQ	

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6.	Washing nozzles	Nozzle insertion into Ampoules not performed properly	Yes	Inadequate Ampoule washing or drying.	No	NA	High	Design ensures that the needle is inserted properly inside Ampoules during washing.	Medium	DQ	• The same shall be verified during qualification. • Needle centring and alignment shall be checked during start of machine and intermittently during routine batch manufacturing, as per SOP	Low	IQ, OQ & SOP	
7.	Washing nozzle	Washing nozzle height could not be adjusted	Yes	The machine may not be suitable for washing of different Ampoule size; washing may not be performed properly.	No	NA	High	Washing nozzle height is adjustable as per different sizes of Ampoules to be washed.	Low	DQ	Functionality shall be checked qualification stages.	Low	OQ	

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8.	Washing	Initial washing of Ampoules from PW or WFI.	No	No impact on process	Operational	Wastage of high quality PW/ WFI.	Medium	• The initial washing step is designed with recirculated WFI and thereafter stages by using PW & WFI. • WFI is used for last stage of washing and reused as recirculated water for initial washing.	Medium	DQ	Functionality shall be checked qualification stages.	Low	OQ	
9.	Washing	Inadequate water quality at one or more wash stations.	Yes	• Washing needles may get blocked. • Inadequate Ampoules washing	No	NA	High	• Fine filters is installed at recirculated water line and PW line, whereas 0.2 µm filter is installed on WFI supply line, respectively. • Water distribution system is built with adequate materials: AISI 316L stainless steel (surface finish ≤0.8 µm Ra), PTFE, silicone.	Low	DQ	Recirculated water, PW and WFI quality shall be checked during qualification and at fix intervals as per SOP.	Low	IQ, PQ & SOP	

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10.	Washing	No provision for storage of recirculated water.	Yes	The required quantity of water and pressure could not be achieved for washing through recirculated water.	No	NA	High	A recirculated water storage tank is provided for storing of recirculated water.	Medium	DQ	WFI from final washing steps, used PW & recirculated water shall be used to maintain water level in recirculated water tank. In case of shortage, fresh WFI shall be used to fill recirculated water tank. .	Low	IQ & OQ	
11.	Washing	Ampoules remain dirty/ glass particles present inside Ampoule/ cleaning insufficient.	Yes	Washing cycle not appropriate. Contamination of Ampoules.	No	NA	High	Ampoule washing is performed for the internal surface as well as for the external.	Medium	DQ	• Washing cycle shall be designed to remove all contaminants. • Efficiency of washing cycle shall be verified during qualification and at frequent intervals. • SOP: Recipe management for different Ampoule sizes.	Low	OQ, PQ & SOP	
12.	Supply of washing media (WFI/ PW)	Inadequate quantity & pressure of WFI/ PW	Yes	Inadequate washing of Ampoules.	No	NA	High	Pressure gauges/ Pressure transmitters is provided on all washing media lines along with alarm provision in case of low pressure.	Medium		Machine should stop in case of insufficient pressure of any of the wash media.	Low	IQ & OQ	

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13.	Supply of washing media (WFI/ PW)	High pressure of WFI/ PW	Yes	Chances of damage to Ampoules & equipment.	EHS	Safety hazard for operator	High	Pressure gauges/ Pressure transmitters is provided on all washing media lines along with alarm provision in case of high pressure.	Medium	DQ	Supply line valve should close and machine shall stop in case of high pressure.	Low	IQ & OQ	
14.	Washing media (WFI)	WFI used for washing is not at high temperature.	Yes	Washing may not be proper.oil based impurities not removed from ampoules.	No	NA	High	Temperature sensor is provided on WFI inlet line to monitor the temperature	Medium	DQ	Machine should be stopped along with alarm provision in case of low temperature of WFI.	Low	IQ & OQ	
15.	Supply of recirculated water	Low pressure of recirculated water	Yes	Inadequate washing of Ampoules.	No	NA	High	• A discharge pump is provided for transferring recirculated water from storage tank to washing station at required pressure. • Pressure gauge/ Pressure transmitter is provided on recirculated water supply line along with alarm provision in case of low pressure.	Medium	DQ	Machine should stop in case of insufficient pressure of the recirculated water.	Low	IQ & OQ	

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16.	Supply of recirculated water	High pressure of recirculated water	Yes	Chances of damage to Ampoules & equipment.	EHS	Safety hazard for operator	High	Pressure gauge/ Pressure transmitter is provided on recirculated water supply line along with alarm provision in case of high pressure.	Low	DQ	Supply line valve closes and machine shall stop in case of high pressure.	Low	IQ & OQ	
17.	Drying	Inadequate or low pressure of compressed air	Yes	Ampoules may not be dried properly; re-contamination of Ampoules possible.	No	NA	High	Pressure gauge/ Pressure transmitter is provided on compressed air inlet line along with alarm provision in case of low pressure.	Medium	DQ	Machine should stop in case of insufficient/ low pressure of the compressed air.	Low	IQ & OQ	
18.	Drying	High pressure of compressed air	Yes	Chances of damage to Ampoules & equipment.	No	NA	High	Pressure gauge/ Pressure transmitter is provided on compressed air inlet line along with alarm provision in case of high pressure.	Low	DQ	Supply line valve closes and machine shall stop in case of high pressure.	Low	IQ & OQ	
19.	Recirculated water tank	Damage to electrical heaters of tank; Failure in attaining required recirculated water temperature.	Yes	Required water temperature may not be attained; inadequate Ampoule washing.	No	NA	High	NA	High	NA	Frequent checking of the wear and tear of the heating element shall be done as per preventive maintenance SOP.	Low	SOP	

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20.	Recirculated water	Ambient temperature recirculated water is used for initial washing.	Yes	Initial washing should be performed with hot water for better results; inadequate Ampoule washing.	No	NA	High	• Electrical heaters is provided on recirculated water tank for heating of water and maintenance at set temperature. • Provision of temperature sensor for monitoring of temperature at re-circulated water tank, along with alarm provision in case of low temperature.	Medium	DQ	• Recirculated water shall be continuously maintained at >50˚C. • Machine shall stop in case temperature falls below 50˚C or in case water is not available.	Low	IQ & OQ	
21.	Recirculated water tank	Low/ No water in recirculated water tank.	Yes	Inadequate Ampoule washing	No	NA	High	Water level sensor is provided for monitoring level inside recirculated water tank.	Medium	DQ	Discharge pump shall stop in case of low level of water inside tank, along with alarm.	Low	IQ & OQ	
22.	Recirculated water tank	Overflow of water in recirculated water tank.	Yes	Water will spread in area, area contamination.	No	NA	High	Water level sensor shall be provided for monitoring level inside recirculated water tank.	Low	DQ	Pneumatic valve shall be installed at inlet line to tank to control/ stop the flow of water in case of high level	Low	IQ & OQ	
23.	Final washing	Chances of recontamination of Ampoules if recirculated water used for final washing step.	Yes	Inadequate washing process	No	NA	High	NA	High	NA	The last rinsing step shall be by using WFI and no recirculation water shall be used.	Low	OQ	

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24.	Washing	Water from previous washing station remains inside Ampoules.	Yes	The contamination may not be removed properly; inadequate washing.	No	NA	High	• Washing of Ampoules is performed in inverted position so that contamination is washed and drained out before going to next station. • Ampoules after each washing stage is dried using filtered compressed air.	Low	DQ	Functionality will be checked during execution of qualification studies.	Low	OQ	
25.	Drying	The Ampoules may remain wet after last washing cycle.	Yes	Contamination of Ampoules may occur.	No	NA	High	The Ampoules are dried internally and externally using filtered compressed air.	Medium	DQ	The residual moisture content of the Ampoules shall be checked and verified during qualification.	Low	OQ	
26.	Drying	Compressed air not as per desired quality	Yes	Particle laden compressed air may contaminate the already clean Ampoules.	No	NA	High	0.2 µm filter is provided on the compressed air supply line for providing required quality for drying of Ampoules.	Low	DQ	Functionality shall be checked during execution of qualification activities	Low	IQ & OQ	

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27.	Filters (0.2 micron on PW & WFI line)	Filter choked/ leakage	Yes	Contaminated washing media may be used for washing; inadequate washing	No	NA	High	Pressure gauges/ Differential pressure transmitter is provided across filter so as to detect leakage/ choking, along with alarm.	Low	DQ	Integrity checking of filter shall be checked regularly as per SOP.	Low	IQ, OQ & SOP	
28.	Pipe emptying	Contamination of piping system	Yes	Residues of cleaning water in piping and resulting moisture may promote dirt accumulation and microbial growth.	No	NA	High	Blow down step is provided so as to drain all water from pipelines after completion of washing process.	Low	DQ	Equipment operation SOP should mention to perform the blow down cycle after completion of operation.	Low	OQ & SOP	
29.	Sampling	Sampling of washing media & air not possible	Yes	Sampling of washing media is a GMP requirement for checking quality.	No	NA	High	Sampling points shall be provided on all washing media lines after final filter and on compressed air line after filter for sampling so as to check its quality.	Low	DQ	NA	Low	IQ	

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30.	Washing	Washing machine speed could not be adjusted or maintained	Yes	Variation in output	Yes	Time loss	Medium	Counters are provided at out feed for counting number of Ampoules washed.	Low	IQ & OQ	• Equipment control system shall be suitable to adjust & maintain the washing speed (number of Ampoules/ minute). • Functionality shall be checked during execution of qualification activities The	Low	IQ & OQ	
Discharge														
31.	Out feed	Maximum accumulation at out feed.	No	NA	Operational	Ampoules may fall off due to high accumulation at out feed	Medium	Out feed occupancy sensor is provided to detect maximum accumulation.	Low	DQ	Ampoule washing machine shall stop in case of full capacity at out feed	Low	IQ & OQ	
32.	Transfer to depyrogenation tunnel	Ampoules get stuck in the discharge wheel/ Guide.	Yes	Damage of Ampoules shall take place.	No	NA	High	• The discharge wheel/ guide is designed in a way to avoid Ampoules from getting stuck. • The discharge wheel movement is synchronized with the main washing wheel movement. .	Medium	DQ	Ampoule jamming should alarmed leading to immediate stopping of machine	Low	IQ & OQ	

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33.	Transfer to depyrogenation tunnel	Washed Ampoules are exposed to environmental air during transfer to tunnel.	Yes	Washed Ampoules may become contaminated again.	No	NA	High	The washed Ampoules is transferred through online conveyor to the tunnel drying zone, which is closed with an acrylic cover (in case distance is <200 mm) or else a ceiling mounted Laminar air flow unit shall be installed over the dead space between Ampoule washing machine and sterilizing tunnel.	Low	DQ	Functionality shall be checked during execution of qualification activities	Low	IQ & OQ	
Equipment Construction- Internal Surface														
34.	Metallic components in direct contact with Ampoules/ washing media/ compressed air	The material may not be suitable; may contaminate Ampoules during or after washing.	Yes	MOC not resistant - Interaction with washing 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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35.	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	
36.	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	
37.	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, 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	

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38.	Joints	Joints are leaking	Yes	May lead to contamination of water which may finally lead to contamination of Ampoule.	Operational	Water may spill in the clean room.	High	• Suitable gaskets are provided for air tight connection and which are replaceable. • Quick release Tri-clover joints are provided in design.	Low	DQ	NA	Low	IQ	
Equipment Construction- External Surface														
39.	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	
40.	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														

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41.	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	
42.	Draining	Stagnant water in pipelines; Improper drain ability or no drain ability	Yes	Residual water may cause microbial growth	No	NA	High	• The washing machine as well as all piping and pumps are constructed as self-draining design. • Proper drainage facility is provided for draining water from the washing stations.	Low	DQ	Sufficient slope shall be provided for all clean media pipelines and the dead legs should be absent.	Low	IQ	
43.	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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44.	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	
45.	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	
46.	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	
47.	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	
48.	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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49.	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	
50.	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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51.	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 Washing 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	
52.	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	
53.	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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54.	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	
55.	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	
56.	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	

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Measuring Instruments														
57.	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	
58.	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	
59.	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														

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60.	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	
61.	Star wheels & Main drive	Star wheels & main drive overload	Yes	Washing 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	
62.	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 Ampoules are provided with quick-fit arrangement.	Low	DQ	The change parts should be identified by non-erasable marking.	Low	IQ & OQ	

Environment & Safety

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63.	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	
64.	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	
65.	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	
66.	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 washing station is covered with a protective, removable polycarbonate covering.	Low	DQ	All moving & electrical parts shall be covered properly.	Low	IQ & OQ	

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67.	Clean Room Conditions	Water vapours during washing may be emitted within the room	Yes	Disturb clean room environment conditions; vapours may condense on the acrylic cover provided over machine and re-contaminate the Ampoules.	No	NA	High	A vapour extraction system is provided with the system.	Low	DQ	Alarm shall be provided in case of malfunction of vapour exhaust system.	Low	IQ & OQ	
68.	Equipment access doors	Polycarbonate access door (over washing stations) may be opened during process.	Yes	▪ If polycarbonate access doors are opened, the clean room temperature and RH conditions may deviate. ▪ Chances of particulate contamination of washed Ampoules	EHS	Operator safety risk, as moving parts shall be exposed.	High	Security switches/ sensors are provided at the polycarbonate access doors with interlock feature with the operation of machine i.e. machine stops immediately if any of the access door is opened.	Low	DQ	Alarm provision shall also be provided for the same.	Low	IQ & OQ	

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69.	Utility	Failure of utility supply is not indicated	Yes	Process parameters may get disturbed	EHS	High pressure may cause accident	High	Various utilities like compressed air, WFI and PW, are interlocked with the process and any failure shall be indicated by alarm.	Low	DQ	Process shouldn't start if any utility is not available.	Low	OQ	
Documentation														
70.	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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71.	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	
72.	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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73.	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 Washing 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
PW	:	Purified Water
WFI	:	Water for Injection
RA	:	Risk Assessment
VFD	:	Variable Frequency Drive
SOP	:	Standard Operating Procedure
AISI	:	American Iron and Steel Institute
Ra	:	Roughness Average
PTFE	:	Polytetrafluoroethylene
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