Risk Assessment Document

Vial Washing Machine

Equipment:…….

RISK ASSESSMENT FOR VIAL WASHING MACHINE

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RISK ASSESSMENT FOR VIAL WASHING MACHINE

1.0 Approval Signature

This document is prepared by the Validation team of the ..... for the project "Integrated Sterile Bulk and Formulations Facility" of ....., under the authority of Unit Head & QA Head. Hence this document before being effective shall be approved by the Unit Head & QA Head.

PREPARED BY		
NAME/ FUNCTIONAL AREA	**DESIGNATION**	**SIGNATURE /DATE**
Validation & QA		
CHECKED BY		
NAME/ FUNCTIONAL AREA	**DESIGNATION**	**SIGNATURE /DATE**
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Unit – Head		
Quality Assurance – Head		

RISK ASSESSMENT FOR VIAL WASHING MACHINE

2.0 Introduction

According to the definition, given in Annex 15, 20 of the EU-GMP-Guide and ICH Q9, a risk assessment is a method to assess and characterise 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 analyses are performed as basic GMP/EHS-Risk assessment, which shall help to identify important GMP/EHS-requirements.

3.0 Aim of the Risk Analysis

At the very basic stage of design the risk assessment is 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 and EHS parameters will be identified and assessed for the risk if not considered in the design or requirements.

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

4.0 Reference Documents

S.No.	Document Title	Document Number
1.	Validation master plan	
2.	Project validation plan	

RISK ASSESSMENT FOR VIAL WASHING MACHINE

5.0 System Description

This risk assessment is conducted for the Vial Washing Machine consisting of the following main components:

S.No.	Description	Purpose
1.	Illuminated table	To inspect the Vials before feeding
2.	In feed tray	Feeding Vials through conveyor on tray and then transferred to the station through infeed screw
3.	Transport system (Grippers)	Transporting the Vials to the needles for washing.
4.	Washing unit	Washing the Vials with recirculated WFI, purified water and Fresh WFI.
5.	Drying Unit	Removal of excess water and Drying with filtered compressed air
6.	Out feed	Washed Vials collection/ infeed of washed Vials into the Tunnel.

In this GMP risk assessment all critical components of the Vial Washing machine, based on the technical details, are listed and rated according to their influence of the product quality, EHS and operational requirements.

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6.0 Participants

Name	Function	Signature

7.0 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:**

It 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:**

  It 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.

This document applies the risk management principles to identify the risks associated with the design, construction and operational features of any equipment, which is going to be procured and installed in the facility.

7.1 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 MOC of the product contact part

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 product contact materials for equipment and containers (eg. Selection of SS grade, gaskets, lubricants etc.)
- Risks related to appropriate utilities and their control (eg. Steam, gases, 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 control system of the equipment
- Risks related to product loss

7.2 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.

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Level	Descriptor	Example detail description
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.

8.0 RISK ASSESMENT

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

Column 1: **Serial number** of Risk analysis 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

component.

Column 4: Verify that whether risk have **GMP impact.**

Column 5: **Justification**: Provide justification for declaring both yes/no for GMP Impact in column 3.

Column 6: For the risk **other than of GMP impact,** write what is the type of risks e.g. EHS, Operational.

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

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

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

Column 9a: **Mitigation Method**: Write the risk mitigation strategy as considered in 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: **Verification:** Write the test point where the risk mitigation strategy will be verified.

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ASSESSMENT FOR VIAL WASHING MACHINE

S. No	Process steps/ component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
General Design of Equipment/ Components:										
1.	Capacity	Insufficient capacity for performing the activity	Yes	Batch requirement cannot meet.	No	NA	High	• Equipment shall be of suitable capacity.	Acceptable	IQ
Process:										
2.	Inspect the Vial before feeding	Defective Vial can move for washing.	Yes	Defective Vial can lead to product contamination.	NO	NA	High	• Illumination table for visual inspection shall be available	Acceptable	IQ
3.	Feeding of Vials	Damage to Vials due to tumbling of Vials on the conveyor	Yes	Minor leakage can be occurred which can't be detected for rejection	No	NA	High	• Appropriate conveying system for Vials like conveyer belt shall be considered	Acceptable	IQ

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S. No	Process steps/ component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
4.	Transportation of Vials	Wrong handling of Vials.	Yes	Damage of Vials	NO	NA	High	• Automatic discharge of Vials should be considered. • Positive gripped with +ve individual V gripper in the discharge system of the washed Vials.	Acceptable	OQ

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S. No	Process steps/ component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
5.	Washing speed	Lacking of Synchronization between tunnel conveyer speed and washing machine speed	Yes	Synchronization is required for process optimization	No	NA	High	• Machine speed should be adjustable for Synchronization with tunnel speed. • If Tunnel conveyor belt stop machine shall give alarm. .	Acceptable	OQ/PQ

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S. No	Process steps/ component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
6.	Washing	Inadequate cleaning	Yes	Product Contamination	No	NA	High	• Provision for cleaning of outer & inner surfaces of the Vials should be there. • Re-circulate water, PW, WFI and compressed air should be used as cleaning media.	Acceptable	IQ
7.	Nozzels	Uncontrolled movement/ operation of nozzles	Yes	Inappropriate cleaning of Vials	No	NA	High	• only spraying when needle is in correct position in Vial	Acceptable	PQ
8.	Infeed	Infeed empty	No	No Impact on product quality	Operational	Utilities wastage	Low	Machine should stop with alarm message.	Acceptable	OQ

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S. No	Process steps/ component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
9.	Vial counting	No provision for counting of Vials	Yes	Counting of Vial required for calculate the batch yield.	No	NA	Medium	Counter system shall be provided to record the number of filled and sealed Vials for better accountability.	Acceptable	IQ
10.	Re-Circulation water	In adequate pressure	Yes	In adequate cleaning	No	NA	High	•Pump shall be provided for achieve required pressure. •Pressure transducer should be available for control the pressure. •Machine should stop with Alarm in case low or high pressure.	Acceptable	IQ/OQ

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S. No	Process steps/ component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
11.	Re-Circulation water	Water Quality failure	Yes	Water of lesser quality can lead to contamination of Vials.	No	NA	High	•Provision of recirculation through 10 micron filter •Heaters shall be provided for Maintenance of water temperature 60°C- 80°C. • Alarm should generate& Machine should stop in case of low or high temperature.	Acceptable	IQ/OQ
12.	Re-Circulation water	Re-circulation tank water low level	Yes	• Improper Cleaning.	NO	NA	High	•Float sensor will be provided to control water level • Solenoid valve installed at the discharge side of the filters in all the lines.	Acceptable	IQ

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S. No	Process steps/ component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
13.	Purified water	Water Quality failure	Yes	Water of lesser quality can lead to contamination of Vials.	No	NA	High	•The purified water shall pass through 5 micron filter • A sampling port should be provided for regular monitoring.	Acceptable	IQ
14.	Purified water	In adequate pressure	Yes	• Low pressure may lead to In-adequate cleaning • High pressure may cause damage to the Vials	No	NA	High	•Pump shall be provided for achieve required pressure. •Pressure transmitter should be available for control the pressure. •Alarm should be generate in case low or high pressure.	Acceptable	IQ/OQ

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S. No	Process steps/ component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
15.	WFI	Water Quality failure	Yes	Water of lesser quality can lead to contamination of Vials.	No	NA	High	• The WFI shall pass through 5 micron filter • A sampling port should be provide for regular monitoring. • Temperature of WFI should be maintained above 80°C.	Acceptable	IQ / OQ
16.	WFI Temperature	WFI Temperature may be less or higher than set limit.	Yes	Low temperature may lead to contamination of water.	EHS	Higher temperature can damage the equipment.	High	• Alarm should be generate in case of low/High temperature.	Acceptable	OQ

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S. No	Process steps/ component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
17.	WFI Pressure	In adequate pressure	Yes	• Low pressure may lead to In-adequate cleaning • High pressure may cause damage to the Vials	No	NA	High	• Pressure transmitter should be available for monitor the pressure. • Alarm should be generate in case low or high pressure.	Acceptable	IQ/OQ
18.	Drying of Vials	Vials not dried adequately	Yes	Product Contamination/ chance to breakage in tunnel	No	NA	High	Compressed air shall be used for removing water from the washed Vials after final rinse.	Acceptable	IQ

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S. No	Process steps/ component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
19.	Compressed Air	Inadequate Supply of air	Yes	Improper Drying	No	NA	High	• Pressure Transmitter shall be there for monitor the compressed air pressure. • Alarm should generate for low or high pressure.	Acceptable	IQ/OQ
20.	Compressed Air	Contaminated compressed air	Yes	Contamination to the product.	NO	NA	High	Supply of compressed air via 0.22 micron filter	Acceptable	IQ

RISK ASSESSMENT FOR VIAL WASHING MACHINE

S. No	Process steps/ component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
21.	Pipe	Ded leg	Yes	Residues of cleaning water in piping and resulting moisture may promote microbial growth	No	NA	High	• The entire piping system shall design to run from high to low, for preventing water stagnation. • Auto drain facility shall be at the end of shift.	Acceptable	IQ/OQ
22.	Joint Sealing	Joints are not adequately sealed	Yes	It will allow accumulation of particles which may lead to contamination.	NO	NA	High	Proper sealing over the joints shall be provided.	Acceptable	IQ

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S. No	Process steps/ component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
23.	Power failure	Auto restart of equipment after power resumption.	Yes	Change of set parameters may occur	Safety	Auto-restart may cause harm to machine, operator and product	High	• On power failure equipment shall come to rest, and should restart with human intervention. • Operator settings should remain unchanged and restored after power resumption.	acceptable	OQ
Control System										
24.	Process automation	Process parameters are not controlled automatically	Yes	Possibility of human error	NO	NA	High	The system shall be PLC based and fully automatic	Acceptable	IQ/OQ
25.	HMI	Process / process status not visible for operating personnel	Yes	Operating personnel must have the process status for control	No	NA	High	HMI shall be provided with adequate display and clean room suitable key board for operation	Acceptable	IQ

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S. No	Process steps/ component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
26.	HMI language	Display language not identified.	Yes	Pre-requisite for the GMP compliant operation	No	NA	High	The language on the display of HMI should be English language only.	Acceptable	OQ
27.	HMI	Recorder Failure	Yes	Basic GMP Requirement (Incomplete/no documentation	No	NA	High	Data backup for process data must be foreseen (electronic recording,21 CFR ,part 11 Compliance)	Acceptable	OQ
28.	HMI Recorder	Recorder failure	Yes	Basis GMP requirement (incomplete / no documentation)	No	NA	High	Diagnostic function test to be a part of qualification activity.	Acceptable	OQ
29.	HMI	Monitoring/recording and documentation of GMP relevant data not possible	Yes	Basic GMP requirement	No	NA	High	• It should be possible to monitor/record GMP Relevant data (Batch records/print outs to be defined. • Print out facility should be available with fade proof prints.	Acceptable	OQ

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S. No	Process steps/ component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
30.	Control System	Control system does not detect failures and generate alarms	Yes	Process optimization and validation is not possible.	No	NA	High	Failure of set parameters gets indicated as alarm and machine stop.	Acceptable	OQ
31.	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 should remain displayed at each process stage. • The flow of the process shall be provided with the help of arrows. • Alarm should also be visualized along with the fault displayed.	Acceptable	OQ
32.	Accessibility to PLC	Parameter settings not identified universally	Yes	Basic GMP requirement	No	NA	High	Parameters settings should be in numeric only.	Acceptable	OQ

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S. No	Process steps/ component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
33.	PLC / Control system	Time measurement works incorrect	Yes	Process insufficient	No	NA	High	• PLC Clock verification • SOP "calibration and maintenance" • Time synchronisation of system	Acceptable	OQ
34.	PLC / Control system	No protection of PLC against manipulation & changes.	Yes	Basic GMP requirement.	No	NA	High	➢ 3 level password protections should be provided. Level 1: for Operator Level 2: for editing Level 3: For admin/engineering level setting.	Acceptable	OQ
Cleaning & Material of Construction:										
35.	Clean ability	Contamination of clean room (non-clean ability)	Yes	Surface of the equipment may encourage dust accumulation	No	NA	High	All external surface shall be smooth finish for easy cleaning	Acceptable	IQ

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S. No	Process steps/ component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
36.	Material Of Construction	The surface is not compatible with the clean room	Yes	May lead to the product and environment contamination	No	NA	Medium	• All metallic non product contact surfaces shall be constructed of 304 grade stainless steel or better. • All metallic contact surfaces shall be constructed of SS304 grade or better.	Acceptable	OQ
37.	Material Of Construction	Gasket MOC not compatible	Yes	Product to be filled will be active with MOC. .	No	NA	High	• Gaskets, seals and O-rings constructed of Food grade polymeric materials.	Acceptable	IQ
Safety:										

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S. No	Process steps/ component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
38.	Noise level	More noise is produced by the equipment during the operation	No	No impact on the product	EHS	High noise may cause deafness and anxiety	Low	• Noise level shall be below 80 db at a distance of 1 m from the equipment	Acceptable	OQ
39.	Earthing	Improper earthing may lead to electric shock	No	No impact on product quality	EHS	Accident may take place due to generation of static charge	High	Proper earthing shall be considered in the design	Acceptable	IQ
40.	Over load	Overload for all pumps, drives and belts	No	No impact on product quality	EHS	Accident can take place.	low	Machine should stop with alarm	Acceptable	IQ/OQ

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S. No	Process steps/ component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
41.	Moving parts & wiring	Moving parts & wiring are not covered	No	NA	EHS	Accident can take place	mediu m	All moving parts & wiring to be covered, door and interlocked Motors should be of reliable make Proper earthing of the equipment	Acceptable	IQ

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S. No	Process steps/ component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
42.	Outer surface	Heated Outer surface	No	NA	EHS	May harm the operator due to higher temperature	Medium	• Polycarbonate guards around the machine with electrical interlocks, so as to maintain outside surface max. 55 °C temp. • Provision of Warning sticker Label/signs on external surface	Acceptable	IQ

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								Mitigation Method	Residual risk level	Verification
43.	Heat emission in room	Room temperature higher than limit	No	NA	Operational	Utility loss	LOW	• Vapor exhaust hood shall be provided as a part of washing section guard.	Acceptable	IQ
Measuring Instruments:										
44.	Measuring Instruments	Measuring Instruments not suitable	Yes	Improper measurements	No	NA	High	• Measuring Instruments must have a suitable measuring range. • Operational range of Measuring instrument shall > equipment working range. • Must have appropriate accuracy.	Acceptable	IQ

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S. No	Process steps/ component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
45.	Measuring Instruments	Measuring instruments not calibrated Re-calibration not possible	Yes	Non calibrated Measuring instruments may lead to false machine functions	No	NA	High	It should be possible to calibrate /recalibrate Measuring instruments (3-point calibration, full loop calibration)	Acceptable	IQ/OQ
46.	GMP relevant measurement sensors	Sensors cannot be dismounted	Yes	Defective sensors must be dismounted for exchange and calibration	No	NA	High	Mounting of sensors must give the possibility for dismounting and replacement. Constructional solution: easy access for calibration activities shall be given.	Acceptable	IQ

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S. No	Process steps/ component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
Documentation:										
47.	User	Faulty operation & maintenance	Yes	SOPs are basic GMP-requirement	No	NA	High	• 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, setting parameters, trouble shooting & maintenance related activities.	Acceptable	IQ
48.	User	Operation SOP does not contain proper information	Yes	User may make a wrong decision.	No	NA	High	• System operation SOP must be reviewed with all aspects and approved. • Vendor shall provide execution support to the user to complete all stages of the qualification report.	Acceptable	IQ

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49.	Vendor	Technical documentation from vendor not adequate	Yes	Adequate technical documentation is basic GMP requirement	No	NA	High	Vendor doc.(English) shall comprise: DQ,IQ and OQ Data sheet Material certificates & surface finish reports O&M manual Calibration certificates 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 Hydro test certificates of pressure parts.	Acceptable	IQ

9.0 Summary and Conclusion

- The Risk analysis is performed to establish the design parameters of the equipment so as to meet the desired performance of the equipment i.e. Vial Washing Machine
- The critical risks pertaining 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 Assesment** performed for the equipment will prevent the risk of failures of critical parameters during design, commissioning, installation, operation and performance of the equipment".*

10.0 Abbreviations

Acronym	Definition
cGMP	Current Good Manufacturing Practice
QA	Quality Assurance
EU-GMP	European – Good Manufacturing Practice
ICH	International committee for Harmonization
EHS	Environmental Health and Safety
GMP	Good Manufacturing Practices
MOC	Material Of Construction
VWM	Vial Washing Machine
SS	Stainless Steel
P&ID	Process & Instrumentation Diagram
PTFE	Poly Tetra Fluor ethylene
db	Decibel
IQ	Installation Qualification
OQ	Operational Qualification
PQ	Performance Qualification
Ra	Roughness average
GA	General Arrangement
GAMP	Good Automated Manufacturing Practices
SOP	Standard Operating Procedures
HEPA	High efficiency particulate air
HMI	Man Machine Interface
PLC	Programmable Logic Controller
O & M	Operation and Maintenance Manual
CFR	Code for Federal regulations
RAD	Risk Assessment Document