Risk Assessment Document for Bin Washer	
Equipment ID:	**Document Number:**
Effective Date:	**Revision No.:** 00

Risk Assessment Document

Bin Washer

Equipment/System ID: ……..

Revision index

Revision	Date	Reason for revision
00		First Issue

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1.0 APPROVAL:

This document is prepared by the Validation team of …… for the project "Oral Solid Dosages Formulations Facility" of …….. under the authority of their Project Manager. Hence this document before being effective shall be approved by the Head QA of …….

PREPARED BY		
NAME/ FUNCTIONAL AREA	**SIGNATURE**	**DATE**
Validation & QA		

CHECKED BY		
NAME/ FUNCTIONAL AREA	**SIGNATURE**	**DATE**
Validation & QA		
Production		
Engineering		
Quality Assurance		

APPROVED BY		
NAME/ FUNCTIONAL AREA	**SIGNATURE**	**DATE**
Head -Quality Assurance		

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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 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 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	

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5.0 SYSTEM DESCRIPTION:

Used bin is oriented in the closed cabinet over the pneumatically operated skid and closed entrance main door for washing. Washing cycle time can be set as per requirements for Plain water, Hot water, Hot Detergent, Process hot water, purified water, Hot air blowing for pre-set time and cold air blowing for pre-set time. In auto mode Bin shall be washed automatically as per sets cycles. There are number of spraying nozzles for washing at all corners & all side walls for outer washing. Top mounting spraying nozzle is fitted with pneumatic cylinder to wash inner surface of the bin, Inner washing nozzle move upward & downward during washing for completely washing of bin. The cabinet is having drain pot with recirculation of water connection with pump. After complete washing cycles bin is dry by passed filtered hot air circulation by air handling unit. Closed washing system for bin have following component:

- Hot water Storage tank
- Air Handling Unit
- Detergent tank

Most of the possible risk concerning the handling/ operation of the Bin washer has been considered in this RAD.

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 (e.g. Water, 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.
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	Low	Medium
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 manage by routine procedures.

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

8.0 PROCESS FOR RISK ANALYSIS:

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 level0**: 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:	**Test Point**: Write the test point where the risk mitigation strategy will be verified.

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								Mitigation Method (9a)	Residual risk level (9b)	Verification (9c)
Bin Washing Chamber:										
1.	Capacity	Insufficient space for Cleaning of Bin Blender	Yes	Adequate space required for the operation is a GMP requirement to conduct error free operation.	Operational	Equipment design should be suitable for the operation.	Medium	The size of the Bin Washer Station should be adequate for loading, cleaning and unloading of Bin blender. The size of the Bin blender should be not more than 500liters.	Acceptable	IQ
2.	Bin Washer chamber	Chamber cannot be drained completely / not fully self draining	Yes	▪ Accumulation of condensate in parts of equipments, risk of contamination. ▪ Complete drainage not possible.	No	NA	High	▪ Appropriate design of chamber as per clean room suitability. ▪ Provision for the high level sensor for opening of drain during cleaning process. ▪ There should be provision for slope for drain point. Drain to be located at the deepest point.	Acceptable	IQ
3.	Bin Washer chamber	Leakage from door	Yes	This is for safety purpose of the chamber.	Yes	EHS	High	▪ Provision for gasket for proper sealing and proper functioning of pneumatic valves. ▪ Bin washer Hydro test report to be provided by the vendor	Acceptable	IQ/OQ

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4.	Bin washer Chamber	Water Pressure not maintained	Yes	▪ Inefficient cleaning ▪ Important parameter for the process.	No	NA	High	▪ Pressure transmitter should be provided to monitor & record the water regularly. ▪ Multistage pump is required for maintaining adequate pressure in the waterline.	Acceptable	IQ/ OQ
5.	Bin washer Chamber	Air Pressure not maintained	Yes	▪ Inefficient cleaning ▪ Important parameter for the process.	No	NA	High	▪ Pressure gauge should be provided to monitor & record the air pressure regularly. ▪ Cycle stop in case of any abnormalities or low air pressure.	Acceptable	IQ/ OQ
6.	Bin washer Chamber	Spray manifold is present at one corner.	Yes	The spray manifold is required for the complete cleaning of the bin.	No	NA	Low	▪ The spray nozzles are uniformly distributed at all corners for external cleaning of the of the bin washer station. ▪ The washing Furry with pneumatic arm to be provided with up and down movement for complete internal cleaning.	Acceptable	IQ

Door:

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								Mitigation Method (9a)	Residual risk level (9b)	Verification (9c)
7.	Doors	Door position failure/ damage	Yes	Contamination of clean room possible by opening both doors.	No	NA	High	▪ Interlock of doors prevents opening of both doors simultaneously. Provision for the pneumatic cylinder for proper locking of the door. ▪ The cleaning cycle will not start if any of the doors remains open.	Acceptable	OQ
8.	Doors	Loading and unloading of unclean bin is not specified.	Yes	Unclean Bin blender may be loaded from the clean side.	GMP risk	Possibility of contamination of clean area.	High	▪ Two Separate hinge doors with locking pins & both necessary interlocked operation will be provided for entry of unclean and for unloading of clean Bin Blender. ▪ Labelling of Bin washer chamber should be done for loading and unloading side.	Acceptable	IQ
Motor:										

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								Mitigation Method (9a)	Residual risk level (9b)	Verification (9c)
9.	Inlet/Supply Motor	Inlet motor blower is not of adequate capacity for supply air.	Yes	The air supply of the Inlet duct is not efficient for proper cleaning.	No	NA	High	▪ The push button shall be provided. PLC/HMI given for controlling the operation. ▪ Alarm should be provided for blower motor overload. ▪ The capacity of motor should be adequate for supplying of hot and cool air after bin washing.	Acceptable	IQ/OQ
10.	Outlet/ Exhaust motor	Outlet motor blower is not of adequate capacity for exhausting the air from the Bin washer station.	Yes	The exhaust motor is not efficient for suction of air from the Bin washer station.	No	NA	High	▪ The push button shall be provided. PLC/HMI given for controlling the operation. ▪ Alarm should be provided for blower motor overload. ▪ The exhaust motor should have more capacity for suction of hot and cool air from the Bin washing Station.	Acceptable	IQ/OQ

Piping:

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								Mitigation Method (9a)	Residual risk level (9b)	Verification (9c)
11.	Piping (Potable and Purified Water)	Inclination of piping too low	Yes	▪ Pipelines cannot be drained completely, ▪ Risk of contamination / microbial growth in piping possible	No	NA	High	Potable and Purified water line should be inclined to the chamber (>1 %).	Acceptable	IQ
12.	Piping (Drain)	Piping system contains dead legs, air pockets	Yes	Pipelines cannot be drained completely. Risk of contamination / microbial growth in piping possible.	No	NA	High	No dead legs or air pockets should be present. Any dead leg shall be of maximum ≤3d.	Acceptable	IQ
Tank:										
13.	WIP tank	There in no provision for checking the low water level in the WIP tank.	Yes	Washing process is not adequate.	No	NA	High	▪ There should be provision for level sensor or transmitter for measuring the low/high level of water inside the tank. ▪ Low water level sensor stop the multistage pump working and cleaning process will stop.	Acceptable	IQ/OQ

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14.	WIP tank	There in no provision for checking the overflow of water from the WIP tank.	Yes	This is required for maintain the proper level of water inside the tank.	No	NA	High	▪ There should be provision for level sensor or transmitter for measuring the high level of water inside the tank to prevent overflow of the water. ▪	Acceptable	IQ/OQ
15.	WIP tank	There is no provision for air vent from the tank.	Yes	There is no provision for removal of air from hot water tank.	Yes	EHS	Low	▪ There should be 0.2 micron vent filter for the removal of air from the tank. ▪ The filter integrity certificate should be provided by the vendor. ▪ The filter integrity testing to be covered through the procedural control.	Acceptable	IQ/SOP
16.	WIP tank	There is no cleaning provision for WIP tank.	Yes	The hot water tank is not easy to clean.	No	NA	Low	▪ The tank spray ball is to be provided with the WIP tank for proper cleaning. The rotation of the spray ball should be 360^0.	Acceptable	IQ

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17.	WIP tank	The temperature of hot water tank is not adequate as per the process requirement.	Yes	The hot water requirement is cleaning process part.	No	NA	Low	▪ There is provision of steam into the jacket for increase the temperature of water. ▪ There should be provision for temperature sensor at pump outlet for monitoring of temperature of the water. ▪ There is provision for recirculation of water into the tank until required temperature is achieved.	Acceptable	IQ
18.	Detergent tank	The detergent tank will overflow.	Yes	The detergent tank overflow is cleaning issue.	No	NA	Low	▪ The level sensor or transmitter should be provided. ▪ The failure condition will indicated by alarm.	Acceptable	IQ/OQ
Filters:										
19.	Filter (Air vent filter)	There is no requirement for the air removal from the WIP tank.	Yes	This is the requirement for removal of air from WIP tank.	No	NA	Low	The air vent filter (0.2 micron pore size) should be provided on the WIP Tank.	Acceptable	IQ

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20.	Filters (Pre Filter and HEPA filter)	Air quality is not adequate.	Yes	Particule laden air	No	NA	High	▪ Pre filters of 10 micron, 5 micron & final HEPA filters (High Temperature application) are provided for air filtration. ▪ Pre-Filter should be detachable for periodic cleaning.	Acceptable	IQ & SOP
21.	Air Flow inside Bin Washer	The air flow from HEPA inside Bin Washer is not sufficient.	Yes	Sufficient clean air supply required for drying of Bin Blender.	No	NA	High	▪ No undue obstruction should be present in the route of clean air through HEPA filter. ▪ Air velocity shall be controlled by dampers to maintain the required velocity at working level. ▪ The velocity of the air through filter should be as per process requirement.	Acceptable	IQ & OQ

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22.	HEPA filter	Choking of HEPA filter	Yes	Non-uniform air distribution leading to contamination of material being transferred.	No	NA	High	▪ Pre-filter with SS perforated grill should be installed at the upstream of HEPA filter to prevent direct load on HEPA filter. ▪ Magnehelic gauge to measure and indicate the differential pressure across HEPA shall be provided.	Acceptable	IQ
23.	HEPA filter placement	Chances of formation of dead space due to inadequate placement of HEPA filters.	Yes	Laminar air flow may get disturbed.	No	NA	Medium	▪ Proper placement of HEPA filter should be considered to attain minimum dead space. ▪ Proper sealing over the joints shall be provided.	Acceptable	IQ & OQ
24.	HEPA Filter Integrity	Failure of Filters	Yes	Admission of contaminated air in to the bin Washing Station.	No	NA	High	▪ Provision of a PAO port for monitoring upstream concentration at the time of integrity testing of the filters. ▪ Filter integrity to be performed during qualification. ▪ Provision for operational control for Filter Integrity Test.	Acceptable	OQ & SOP

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Cleaning:										
25.	Loading of Bin	Loading of the uncleaned Bin blender is not GMP compliant	Yes	Loading will lead to the violation of the GMP.	No	NA	High	▪ Loading of the Bin blender should be done by using ramp. ▪ Loading of Bin Blender should be done from unclean side.	Acceptable	IQ/OQ
26.	Cleaning	Cleaning media could not reach to all parts of the vessel.	Yes	Cleaning not uniform inside and outside the Bin blender. Product contamination possible.	No	NA	High	• Spray balls (with 360° reach) should be provisioned inside the vessel on the CIP media inlet line, so as to reach every part of the vessel with the help of up and down movement pneumatic arm. • Nozzles provision is given on inner chamber of the Bin washing station for outside cleaning of the Bin blender.	Acceptable	IQ/ OQ

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27.	Cleaning	CIP cycle time not controlled / measured	Yes	Bin Blender is not cleaned/ washed properly due to cycle time too short.	No	NA	High	• CIP process should have configurable parameters for Cleaning Process. • The complete process should be controlled through automatic system.	Acceptable	OQ
28.	Cleaning	Final rinsing step is not with Purified Water.	Yes	Inefficient cleaning cause product contamination.	No	NA	High	• The initial cleaning is done with potable and purified water. • Final rinsing was given with purified water for avoiding contamination into the product.	Acceptable	OQ
29.	Cleaning	Slope of cleaning media piping too low	Yes	Pipelines cannot be drained completely, Insufficient cleaning, Risk of contamination / microbial growth in piping possible	No	NA	High	• Dead legs, air pockets, should be minimized (preferred 1.5D); dead volume minimised valves. • Drains should be located at the deepest points. • Inclination to vessel or drain points (>1:100).	Acceptable	IQ

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30.	Cleaning with Compressed Air	Compressed air supply is not sufficient.	Yes	Removal of water from bin blender is not possible.	No	NA	High	▪ Compressed air pressure should be as per process requirement. ▪ The continuous compressed air supply is required for during this stage. ▪ Provision of alarm should be there for detection of low compressed air pressure.	Acceptable	OQ
31.	Compressed air	Compressed air supply is contaminated.	Yes	Product contamination.	No	NA	High	▪ Compressed air should be filtered through 0.2 micron filter to avoid contamination of Bin blender.	Acceptable	OQ

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32.	Drying with Hot Air	Hot air supply is not sufficient.	Yes	Drying of bin blender is not possible.	No	NA	High	▪ The continuous Hot air supply is required during this stage for complete drying of the bin blender. ▪ There should be provision for temperature sensor on the inlet supply for monitoring of temperature of hot air. ▪ Any fault condition of hot air system is indicated by audio visual alarm.	Acceptable	OQ
33.	Dry Hot Air	Hot air supply is contaminated.	Yes	Contaminated hot air causes product contamination.	No	NA	High	There should be provision for HEPA filter on the inlet supply of AHU to avoid contamination of air.		

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34.	Drying with cool Air	Cool air supply is not sufficient.	Yes	Drying and cooling of bin blender is not possible.	No	NA	High	▪ The continuous cool air supply is required during this stage for complete drying of the bin blender. ▪ Any fault condition of cool air system is indicated by audio visual alarm. ▪ The bin blender should be at room temperature before completion of cleaning cycle.	Acceptable	OQ
35.	Dry cool Air	Cool air supply is contaminated.	Yes	Contaminated cool air causes product contamination.	No	NA	High	There should be provision for HEPA filter on the inlet supply of AHU to avoid contamination of air.	Acceptable	OQ
36.	Bin Washing Cycle End	No control on Process cycle.	Yes	Process cycle will not end automatically.	No	NA	High	▪ The automatic system with alarm provision should be provided for confirmation of cycle End.	Acceptable	OQ

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37.	Unloading of Bin	Unloading of the cleaned Bin blender is not GMP compliant	Yes	Unloading will lead to the violation of the GMP.	No	NA	High	▪ Unloading of the Bin blender should be done using the ramp. ▪ Unloading of Bin Blender should be done in the clean side.	Acceptable	IQ/OQ
Equipment Constructions and Utilities:										
38.	Bin Washer chamber inclusive doors and connected parts / equipment in direct contact with chamber and piping	The material of internal surface such as washer chamber including doors and connected parts/ contact parts is not suitable.	Yes	MOC not resistant - Interaction with media possible	No	NA	High	▪ Metallic critical contact surfaces shall be constructed of SS 304 or better grade stainless steel, electro polished, orbital welded. ▪ The suitability of the materials shall be proven by certificate / manufacturers declarations. ▪ Material shall be temperature resistant. ▪ Supporting structure and non contact parts shall be of SS 304 or better. ▪ Piping should be SS 304 or better grade.	Acceptable	IQ

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39.	Polymeric materials	Polymeric materials are not compatible and are not replaceable	Yes	Shall lead to contamination of material to be cleaned.	No	NA	High	• Gaskets and O-rings coming in direct / indirect contact surfaces shall be made up of food grade polymeric materials only and shall be high temperature and pressure resistant. • The easy change of gaskets must be possible. • Vendor shall provide the certificate for food grade polymeric material.	Acceptable	IQ
40.	Welding Joints	Uneven and improperly ground weld joints will form a space for dust accumulation	Yes	Weld joints not grounded properly and are not passivated.	No	NA	High	• All welds shall be ground finished and properly passivated and orbital welding should be done. • Welding to be done using high purity inert gas.	Acceptable	IQ

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41.	Bin washer Chamber inclusive doors and connected parts / equipment in direct contact with chamber, piping	Surface finishing insufficient	Yes	Micro-organisms may accumulate on metallic surfaces	No	NA	High	▪ Surface roughness, Ra ≤ 0.8 µm, proven by certificates for metal parts. ▪ Crevice free smooth, rounded corners & smooth surface. ▪ Surfaces must be plain with rounded corners and without gaps. ▪ Pipeline internals should be mill finished.	Acceptable	IQ
42.	Lubricant	Material of lubricant not suitable	Yes	Leads to contamination	No	NA	High	• Lubricant used in the equipment shall be food grade • Design shall ensure lubricant used in the equipment must not come in potential product contact surface. • Food grade certificate shall be provided for lubricant.	Acceptable	IQ

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43.	Surface	External surface of equipment is not suitable	Yes	May lead to the clean room contamination	No	NA	Medium	▪ Metallic critical contact surfaces shall be constructed of SS 304 or better grade stainless steel, electro polished, orbital welded. ▪ The suitability of the materials shall be proven by certificate / manufacturers declarations. ▪ Material shall be temperature resistant up to 100 ºC. ▪ Supporting structure and non contact parts shall be of SS 304 or better.	Acceptable	IQ
44.	Finishing	External finish of equipment is not proper.	Yes	May lead to the microbial growth	No	NA	Medium	External surface shall be free from sharp edges, corners, crevices etc., all metallic external surface shall be matt or mirror finished.	Acceptable	IQ

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45.	Potable Water	Potable water pressure is not adequate for the cleaning of Bin blender.	Yes	Proper cleaning of the Bin blender not possible.	No	NA	High	▪ There should be provision of suitable capacity pump to meet the required potable water pressure during cleaning cycle. ▪ Provision for monitoring of pressure of potable water supply. ▪ If any faulty condition occurred, the cleaning process will stop with audio visual alarm.	Acceptable	IQ/ OQ
46.	Purified Water	Purified water pressure is not adequate for the cleaning of Bin blender.	Yes	Proper cleaning of the Bin blender not possible.	No	NA	High	▪ There should be provision of suitable capacity pump to meet the required purified water pressure during cleaning cycle. ▪ Provision for monitoring of pressure of purified water supply. ▪ Due to any faulty condition, cleaning process stopped with audio visual alarm.	Acceptable	IQ/ OQ

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47.	Compressed Air	Compressed air pressure not adequate	Yes	Cleaning requirement	No	NA	High	Pressure gauge/ pressure switch to be provided at plant inlet line for monitoring and controlling of compressed air pressure, along with alarm provision.	Acceptable	IQ/ OQ
48.	Hot/ Cool Air	Hot/Cool air temperature not adequate for drying of Bin Blender.	Yes	Proper drying of the Bin blender not possible.	No	NA	High	Temperature gauge to be provided at inlet line for monitoring of hot air pressure.	Acceptable	IQ
49.	Cleaning	Difficult cleaning	Yes	Retention of particles inside the bin blender, contamination of clean room possible	No	NA	High	• Design of the Bin Blender should enhance cleaning feasibility by providing minimum sharp corners, minimum crevices & smooth finished surface. • Parts which are required for cleaning are provided with quick fixing arrangement. • All bolts, nuts on the exterior part of equipment are provided with cap head or cap nut.	Acceptable	IQ

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50.	Labelling of components	Labelling of components/ media inappropriate	Yes	Prerequisite for qualification & maintenance	No	NA	Medium	• Unique identity number / flow direction must be on components / media, operator panel, etc. (e.g. according to P&ID) • Labels affixed on the equipment should be heat resistant. • All labelling in English language and according to project standard.	Acceptable	IQ
Control System:										
51.	Process automation	Process parameters are not controlled automatically.	Yes	Possibility of human error leads to a process which is not validated	No	Na	High	• The equipment shall control & detect failure mode automatically. • The System shall be PLC based and fully automatic.	Acceptable	IQ & OQ
52.	Human-machine Interface	Process / process status not visible for operating personnel.	Yes	Operating personnel must have knowledge on the process status	No	NA	High	HMI shall be provided with adequate display and clean room suitable key board for operation and entering process parameters.	Acceptable	IQ
53.	Human-machine Interface	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

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54.	Human-machine Interface	Recorder failure	Yes	Basis GMP requirement (incomplete / no documentation)	No	NA	High	• Data backup for process data must be foreseen (electronic recording, 21 CFR part 11 compliant). • Diagnostic function test to be a part of qualification activity.	Acceptable	OQ
55.	Human-machine Interface	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 (e.g. recorder with compliance to GAMP 5 / 21 CFR, Part 11 etc.) • Batch records / print outs to be defined. • Printout facility should be available with fade proof prints.	Acceptable	OQ
56.	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 and printed as alarms and machine stops. • Alarm shall be provided in case of any instrument not working properly, loss of communication or broken wire.	Acceptable	OQ

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57.	PLC / Control system	Power failure / emergency stop	Yes	Process out of specification	Safety	Unsafe if start automatically on restoration of power	High	• Operator settings unchanged and restored after emergency stop / power failure; • Alarm message; • On power failure equipment should come to rest to protect operator, equipment itself & the articles. • Provision for UPS to the control system. • Machine must not start automatically without operator intervention after incident • Provision for Maintenance and operation of Bin Washer.	Acceptable	OQ/ SOP
58.	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. • Alarm should also be visualized along with the fault displayed.	Acceptable	OQ

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59.	PLC / Control system	Malfunction	Yes	Correct function basic requirement for GMP-compliant operation	No	NA	High	• Supplier assessment (quality management system for software and control system hardware development) • Input/ Output test implementation in qualification activities • The system must contain all necessary protection devices to ensure that the equipment and article remain in safe condition. • Manual mode operation should be provided for the equipment.	Acceptable	OQ
60.	Accessibility to PLC	Parameter settings not identified universally	Yes	Basic GMP requirement	No	NA	High	Parameters settings should be in Alphabetic/numeric only.	Acceptable	OQ
61.	PLC / Control system	Time measurement works incorrect	Yes	Process insufficient	No	NA	High	• PLC Clock verification • Provision operational control for calibration and maintenance. • Time synchronisation of system.	Acceptable	OQ/ SOP

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62.	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 settable parameters. ➢ Level 2: for editing cycle parameters. ➢ Level 3: for admin/ engineering level setting.	Acceptable	OQ
63.	Control system	The machine operates in same manner, even when the different task is required.	No	NA	Operational	Wastage of the utilities, not required in the operation.	Medium	▪ PLC should be equipped with different cycles as per different requirements- ➢ Bin Wash Cycle	Acceptable	OQ
Measuring Instruments:										
64.	Measuring Instruments	Measuring instruments not suitable	Yes	Improper measurements	No	NA	High	▪ Measuring Instruments must have a suitable measuring range. ▪ Measuring Instruments must have appropriate accuracy.	Acceptable	IQ
65.	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 should be calibrated (full loop calibration). ▪ Measuring instruments should be suitable for Re-calibration.	Acceptable	IQ/OQ

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66.	GMP relevant measurement instruments	Instruments cannot be dismounted	Yes	Defective instruments must be dismounted for exchange and calibration	No	NA	High	▪ Mounting of instruments must give the possibility for dismounting and replacement. ▪ Constructional solution: easy access for re-calibration activities shall be given.	Acceptable	IQ
Maintenance:										
67.	Maintenance	Malfunctions due to worn parts	Yes	Basic GMP requirement	No	NA	High	▪ Bin Washer station shall be easy to maintain. ▪ Preventive maintenance procedure should be available. ▪ Vendor to provide special tools for maintenance. ▪ The unit must contain necessary protection devices to ensure that the equipment & the article remain in a safe condition.	Acceptable	IQ/ SOP

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68.	Filter removal	The removal filters is not possible	Yes	Pre-filters needs to be regularly cleaned. HEPA filters needs to be replaced in case of any damage.	No	NA	High	▪ The Bin Washer should have access panel for easy servicing or removal of Exhaust filter and HEPA filter. ▪ Pre-filter should be of detachable type and easily cleanable.	Acceptable	IQ
69.	Blower	Blower malfunction	Yes	Operation will be disturbed.	No	NA	High	Visual indication should be available in case of blower trip or malfunction, along with audio alarm.	Acceptable	IQ & OQ
Safety :										
70.	Electrical system	Electrical systems are not verified for safety	No	It will not affect the quality of product.	EHS	May lead to an accident	Medium	All electrical systems shall be tested for safety and shall be provided with safety markings.	Acceptable	IQ
71.	Noise level	Noise level liberated by the system is high.	No	It will not affect the final quality of product.	EHS	Heavy noise will cause problems to the service persons	Medium	The noise liberated by the system shall not be more than 80 db from 1meter from the system.	Acceptable	OQ

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								Mitigation Method (9a)	Residual risk level (9b)	Verification (9c)
72.	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 with alarm to be installed on accessible area.	Acceptable	IQ/ OQ
73.	Power Failure	Power failure	Yes	Can lead to contamination of the material being dispensed/ sampled or the clean room	No	NA	High	▪ On power failure equipment should come in fail safe condition & on recovery of the power failure the equipment should re-start and retain the condition. ▪ UPS supply should be provided for continuous operation.	Acceptable	IQ/OQ
74.	Steam	High steam pressure	No	Does not impact the quality of product.	Safety & Operational	Environmental & operator safety hazards	High	▪ Steam pressure regulated valve shall be installed on pure steam line. ▪ Pressure gauges to be provided on the Steam line to indicate the line pressure. ▪ The insulation wool is required to insulate the jacket to avoid heat transfer to the environment.	Acceptable	IQ

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75.	Bin Washer station	High emission of heat	Yes	Disturb room temperature and relative humidity.	EHS	Environment & Personnel safety hazards	High	▪ Proper insulation and outside temperature should not be more than 45 ºC. ▪ SS 304 cladding should be provisioned for insulation. ▪ Insulation material should be resin bounded Glass wool/ Rock wool.	Acceptable	IQ
76.	Moving Parts & Electrical parts	Appropriate covering of the moving & electrical parts is not provided.	No	Does not have impact on quality of the product	EHS	May lead to an accident	High	Appropriate covering for all the moving & electrical parts to be provided.	Acceptable	IQ
Documentation:										
77.	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	OQ/ SOP

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78.	User	Operation SOP does not contain proper information and user may operate system	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	OQ
79.	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 should not start without password. • Key-switch should be provided for system power up.	Acceptable	IQ/ OQ

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80.	Documentation	Technical documentation from vendor not adequate	Yes	Adequate technical documentation is basic GMP requirement	No	NA	High	• Vendor documentation shall comprise: - Material certificates - DQ, IQ & OQ protocols - Operation and maintenance instructions - Spare parts list - Operating manual of bought out components - Welding report - Hydro test certificate - Functional design specification - List of failure indications - Surface finish test reports - HMI functions with screen shots • Drawings - P&I-diagrams - Electrical diagrams - GA diagram • Calibration certificates of measuring instruments	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. Bin washer.
- 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 Assessment** performed for the equipment will prevent the risk of failures of critical parameters during design, commissioning, installation, operation and performance of the equipment"*

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10.0 ABBREVIATIONS:

Acronym	Definition
CFR	Code of Federal Regulation
CIP	Cleaning in Place
db	Decibel
DQ	Design Qualification
EHS	Environment Health and Safety
EU-GMP	European Good Manufacturing Practices
GA	General Arrangement
GAMP	Good Automated Manufacturing Programme
GMP	Good Manufacturing Practice
HEPA	High Efficiency Particulate Air
HMI	Human Machine Interface
ICH	International Conference of Harmonization
IQ	Installation Qualification
LED	Light Emitting Diode
LLP	Limited Liability Partnership
MOC	Material of Construction
OQ	Operational Qualification
PAO	Poly Alpha Olefin
P&ID	Piping And Instrumentation Diagram

Acronym	Definition
PLC	Programmable Logic Controller
PVP	Project Validation Plan
QA	Quality Assurance
RAD	Risk Assessment Document
SOP	Standard Operating Procedure
SS	Stainless Steel
UPS	Uninterruptable Power Supply
VMP	Validation Master Plan
WIP	Washing in Place