Risk Assessment Document Dispensing, Sieving & Blending Isolator Equipment ID:

Revision index

Revision	Date	Reason for revision
00		First issue

FAILURE MODE EFFECT ANALYSIS FOR DISPENSING, SIEVING & BLENDING ISOLATOR

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FAILURE MODE EFFECT ANALYSIS FOR DISPENSING, SIEVING & BLENDING ISOLATOR

1.0 Approval

This document is prepared by the validation team of ……for the project 'OSD Formulations Facility' of ……..under the authority of their Project Manager. Hence, this document before being effective shall be approved by the QA team of ……..and authorized by the appropriate Project Authority.

PREPARED BY		
NAME	**DESIGNATION**	**SIGNATURE /DATE**

CHECKED BY		
NAME	**DESIGNATION**	**SIGNATURE /DATE**

APPROVED BY		
NAME	**DESIGNATION**	**SIGNATURE /DATE**

FAILURE MODE EFFECT ANALYSIS FOR DISPENSING, SIEVING & BLENDING ISOLATOR

2.0 Introduction

According to the definition, given in Annex 15, 20 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 is performed as basic GMP/EHS-Risk assessment, which shall help to identify important GMP/EHS-requirements.

3.0 Aim of the 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.

4.0 Reference Documents

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

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5.0 Equipment Description:

Dispensing, Sieving & Blending Isolator is designed for dispensing, sampling & sieving of active potent ingredients which needs high containment transfer. Dispensing, Sieving & Blending Isolator is having a negative pressure w.r.t. room and air leakage rate not more than 5% of isolator volume

Dispensing, Sieving & Blending Isolator consists of two sections i.e. a Dispensing and blending section and a sieving section. There is no physical barrier between the two sections, but the Blending section is double height to accommodate the blender. The chamber has provided HEPA filters supported by fine filter. Wash nozzle and hose is used for manual cleaning of chamber. There is drain outlet in the base of chamber. Sieving section has series of glove ports, weighing balance, Spray gun for wash in place (WIP). IBC with RTP passive at charging & discharging are docked to an active at the base of the Isolator using a fixed jacking hoist to ensure valve integrity.

6.0 Participants

Name (block letters)	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 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.

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

Level	Descriptor	Example detail description
		• Used in the initial stage of operation, however it may affect the final output but those are not used for final release of output. • Effect on environment such as clean room.
3	Major	• Features having direct impact on product quality/ outcome of equipment like contact parts MOC, Surface finish, Control system, Process air quality etc. • Failure could lead to regulatory non-compliance. • Loss/ damage to equipment or its critical sub-components • Critical instruments not calibrated or not of desired range or accuracy. • Proper supporting documentation not provided. • Major effect on personnel health

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

Qualitative risk analysis matrix – level of risk*

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

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

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

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

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

8.0 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 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 component.
Column 4:	Verify that whether there is **GMP risk.**
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 risk,** write what is the other 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.

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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
Charging										
1.	Charging of raw material container is not possible.	Provision not available for placing the raw material container in isolator	Yes	Basic requirement	No	NA	High	Proper transferring system shall be considered in the design .transfer hatch / liner shall be used for transfer of material	Acceptable	IQ/OQ
2.	Transfer of API containers from warehouse to dispensing room	Wrong container is transferred with respect to material identification, container integrity and material receipt number for FIFO.	Yes	Basic GMP requirement	EHS	In case the container is not integral	Medium	SOP: material storage and dispensing manufacturing instructions: checklist	Acceptable	SOP
3.	Lighting	Light is not suitable	Yes	Basic GMP requirement	No	NA	High	Proper lighting (min 500 lux)shall be provided	Acceptable	IQ/OQ
4.	Weighing platform	Weighing platform is not shockproof	Yes	Inaccurate weighing possible	No	NA	High	Anti-vibration platform is included	Acceptable	IQ
5.	Visibility in the chamber	Visibility in the chamber is poor	Yes	Readability of weight is critical process requirement	No	NA	High	Transparent material shall be used to ensure visibility.	Acceptable	IQ

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6.	Height of isolator	Isolator height is not suitable to dock the material collection bin	Yes	Basic requirement	No	NA	Medium	Working height is considered to accommodate a vessel of specified height	Acceptable	OQ
7.	Docking not gastight	Docking not gastight	No	Does not have any impact on product quality	EHS	Contamination of air with high potent drug	High	Supplier to ensure the gastight closure of isolator. Regular leak test schedule for door gasket replacement SOP: Preventive maintenance to include schedule of leak test and gasket replacement.	Acceptable	IQ/OQ
8.	Size of isolator and container	Docking cannot be done due to mismatched aperture diameter between isolator and container	Yes	Basic requirement	EHS	Contamination of external/ room with high potent drug	High	Aperture on isolator, container and split valve will be kept same for correct interfacing	Acceptable	IQ
9.	Chamber space of isolator	Isolator chamber space is not suitable to keep the material container	Yes	Design adequacy	No	NA	Medium	Design considered with all operational requirements	Acceptable	IQ

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10.	Size of sleeve	Sleeve port size is not suitable to transfer minimum 5 kg powder materials, HEPA filter and waste material.	Yes	Design adequacy	No	NA	Medium	Design considered a size of minimum 200 mm sleeve port	Acceptable	IQ
11.	Opening of Isolator doors	The opening of isolator door is not warned	No	Does not have any impact on the quality of the product	EHS	Contamination of external/ room with high potent drug. Operator safety	Medium	The opening of isolator door should be alarmed and equipment should come to rest with exhaust running.	Acceptable	OQ
12.	Weighing and weighing balance	Balance is not suitable for weighing in required range of quantity	Yes	Affect weighing accuracy	No	NA	High	Design considered the range and accuracy	Acceptable	IQ / OQ
13.	Balance readings	Balance readings are not visible	Yes	Critical requirement for weighing accuracy	No	NA	Medium	Reading should be visible	Acceptable	OQ
14.	Balance level	Balance could not be leveled properly	Yes	Affect weighing accuracy	No	Na	High	Balance base to be provided with level adjustment screw and spirit level.	Acceptable	IQ

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15.	Printer interface	Print of weight cannot be taken	Yes	Documentation requirement; however can be manually recorded	No	NA	Medium	In case printout is not available, weight will be recorded in batch manufacturing record manually.	Acceptable	IQ/SOP for weighing
16.	Hand gloves	Uncomforted operation with hand gloves, chances of material spillage.	No	No impact on weighed quantity	Operational	Loss of material	High	SOP: Dispensing of active ingredient in Isolator Training of operators for the operations in isolator	Acceptable	IQ/OQ
Vibro Sifter										
17.	Charging of material	Spillage during charging of material	Yes	Loss of quantity of the materials, result in disturbed proportion of the same, area contamination	No	NA	High	charging chute will be designed wide enough for appropriate feeding method of input materials	Acceptable	IQ / PQ
18.	Charging vent	Material spreads out from the charging vent	Yes	Loss of quantity of the materials, result in disturbed proportion of the same, area contamination	No	NA	High	Lid/Cover will be provided to stop powder to spreading out	Acceptable	IQ / PQ

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19.	Sifting	Dead spots formed	Yes	Material will remain non-sifted	No	NA	Medium	• Equipment should be designed so that there would not be any dead spot • Sieve shall be located within the isolator with outlet connected directly to the outlet port • Alarm shall be provisioned for malfunction /start	Acceptable	OQ
20.	Frame and sieve assembly	Frame and sieve assembly get loosen during operation	Yes	Malfunctioning of the sifting process	EHS	Accident due to detachment of parts. Product exposure.	High	Secure locking of the frame, gasket and sieve assembly will be considered so that it will remain tighten during entire sifting operation	Acceptable	IQ / OQ
21.	Discharge chute	Powder spreads out during transferring	Yes	Product loss	EHS	Product exposure	High	Discharge chute shall be designed to avoid the spillage using silica latex sleeve	Acceptable	IQ / PQ

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22.	Product discharge	Incomplete discharge of the product	Yes	Uniformity of content of product may get disturbed	No	NA	Medium	Vibrosifter will be designed to facilitate complete discharge of the product. Tangential slope will be provisioned at the discharge.	Acceptable	IQ / PQ
Blender										
23.	RPM of blender	With respect to process requirement desired RPM cannot be set and monitored.	Yes	Process requirement for effective mixing.	No	NA	High	RPM should be set and controlled from control panel.	Acceptable	OQ
24.	Timer	Blending time cannot be set	Yes	Basic requirement	No	NA	High	Timer should be set and controlled from the control panel.	Acceptable	OQ
25.	Timer	Blending time gets reset before completion of blending cycle.	Yes	Correct Blending time cannot be achieved which will lead to improper mixing.	No	NA	High	Provision to be provided to continue the blending from where it was stopped due to breakdown or any other reason. Memory backup should be facilitated.	Acceptable	IQ / OQ
26.	Blending	Upon completion of blending operation blender stops in undesired direction	No	Does not have any impact on the quality of the product	Operational	Difficulty in unloading	Medium	After completion of the blending time, the discharge valve should rest at bottom side	Acceptable	OQ

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								Mitigation Method	Residual risk level	Verification
27.	Sampling	Sampling is not possible from the blender	Yes	Sampling is required for validation study and routine assessment sample.	No	NA	High	Provision for manhole should be provided to assist sampling.	Acceptable	IQ / OQ
Controlling system										
28.	Control system	Control system do not detect failures	Yes	Basic requirement	No	NA	Medium	Failure mode detection is considered	Acceptable	OQ
29.	Machine operation	Operator and staff is not trained	Yes	Untrained operators may not operate equipment properly	Operational/ EHS	Chances of accidents	High	Proper training to be imparted with operator and staff by the vendor	Acceptable	OQ
Discharge										
30.	Discharge of dispensed material	Discharge of dispensed material in closed condition in IBC not possible	No	Does not have any impact on the quality of the product	EHS	Staff protection	High	• Rapid transport port shall be provided • RTP active and passive shall be provided for IBC • Jacking hoist shall be provided to support easy lifting of IBC	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
Cleaning and material of construction										
31.	Material of chamber	Material of chamber not suitable	Yes	May lead contamination	No	NA	High	• SS316 or better grade shall be provided for the contact parts with 0.4 Ra mirror finish • Non contact parts shall be SS304 or better • All bolts, nuts on the exterior part of the equipment will be • MOC certificate shall be provided	Acceptable	IQ
32.	Transfer of material	Isolator is not in cleaned condition	Yes	Cross contamination	No	NA	High	SOP: Operation & cleaning of dispensing sieving & Blending Isolator	Acceptable	To record in checklist of batch mfg records/ SOP

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								Mitigation Method	Residual risk level	Verification
33.	Cleaning of chamber	Chamber is not cleanable	Yes	May cause cross contamination of product	No	NA	High	Design of equipment should enhance cleaning feasibility by providing minimum sharp corners, minimum crevices & smooth finished weld joints	Acceptable	IQ
34.	Isolator surface	Isolator surface is not compatible with decontaminating agents	Yes	Contamination	No	NA	High	MOC selection is considered with decontaminating agents	Acceptable	IQ
35.	Draining of water	During cleaning water is not drained from the surface	Yes	Chances of microbial growth if water is not drained completely	No	NA	High	A suitable slope towards drain port is considered	Acceptable	IQ
36.	Isolator surface	Isolator surface is not dried	Yes	Require dryness for operation. Chances of microbial growth if surface is not dried	No	NA	High	Isolator should be suitable to connect with compressed air	Acceptable	IQ

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37.	Connection of utility to chamber	Chamber cannot be connected with clean media (potable water, purified water, compressed air) for cleaning	Yes	Contamination	No	NA	Medium	Nozzle and hose for connecting clean media shall be provided for manual cleaning	Acceptable	IQ
38.	Cleaning of balance	Balance base is not cleanable and not compatible with decontamination agent	Yes	Contamination	No	NA	High	MOC of balance base should be compatible with decontaminating agent	Acceptable	IQ
Safety:										
39.	Weighing chamber	Chamber is gastight	No	Equipment is installed in clean area	EHS	Emission of high potent drug	Medium	• Supplier to ensure the gastight closure of isolator • Regular leak test • Schedule for door gasket replacement • SOP: Preventive maintenance to include schedule of leak test and gasket replacement	Acceptable	IQ/OQ

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40.	HEPA filters and electrical sockets	During cleaning weighing balance, HEPA filter and electrical sockets are not protected from water	No	This is a special requirement for these components to protect from water	Operational	Components or component performance is not compatible with water	High	• SOP: Precaution to be taken during cleaning • Alarm shall be generated in case of filter blockage	Acceptable	OQ/SOP
41.	Wash water	Wash water pass through the plastic sleeve port	Yes	If not detected dispensed material may get wet	No	NA	High	A suitable cover over sleeve port is considered	Acceptable	IQ
42.	Maintenance	Chamber is not accessible during breakdown maintenance	Yes	GMP requirement	No	NA	High	Isolator will be provided with access door	Acceptable	IQ
43.	Joint gaskets	Joint gaskets are not replaceable	Yes	Maintenance requirement	EHS	If damaged there is chance of product leakage	Medium	Gasket will be replaceable	Acceptable	IQ
44.	Gaskets	Gaskets are not compatible with material handled in isolator	Yes	Contamination	EHS	If damaged, there is a chance of product leakage	High	Gaskets should be food grade selected gaskets should be compatible with decontaminating and cleaning agent	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.	Hand gloves	Hand gloves are not replaceable	Yes	Contamination in case of damage	EHS	Product leakage	High	Hand gloves should be replaceable SOP: Preventive maintenance (for visual checking and replacement)	Acceptable	IQ
46.	Hand gloves	Pinhole leaks in hand gloves are not detectable	No	Does not have any impact on product	EHS	Product leakage	High	Hand gloves should be suitable for in place integrity test	Acceptable	OQ
47.	Hand gloves	Hand glove material is not compatible with material to weigh	Yes	Material contamination	No	NA	Medium	• Hand gloves should be inert to product • Doubled layer glove shall be considered	Acceptable	IQ
48.	Hand gloves	Hand glove material is not compatible with decontaminating agent	Yes	Material contamination	No	NA	Medium	Hand gloves should be inert to decontaminating agent	Acceptable	IQ
49.	Balance body	Balance body is not compatible with decontaminating agent	Yes	Material contamination	No	NA	Medium	SOP: During cleaning, balance body will be wrapped and taken out	Acceptable	OQ/ SOP
50.	Balance cable	Balance cable is not compatible with decontaminating agent	Yes	Material contamination	No	NA	Medium	SOP: During cleaning, balance cable will be wrapped and taken out	Acceptable	OQ/ SOP

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51.	Lubrication	Lubricants quality not good	No	May leads to contamination of product	No	NA	High	• Lubricants must be food grade and non – toxic • Food grade certificate shall be available	Acceptable	IQ
52.	Air handling system	Design does not prevent leakage of powder in the environment/ System does not work properly	Yes	Chances of cross contamination	EHS	Emission of powder	High	• All ducting must be leak proof Outlet and exhaust supported with HEPA filter • Blower shall be able to generate required CFM of supplied air • Speed shall be controlled by VFD • Alarm shall be generated in case of Blower VFD not working properly	Acceptable	IQ, OQ
53.	Waste water drainage	Rinse water drain in wrong drain	No	Does not have any impact on the quality of the product	EHS	Will not be properly treated	Low	Isolator drain line will be directed towards the correct drain	Acceptable	Facility Qualification
54.	Air break	No air break maintained	Yes	Back suction of waste water	No	NA	Low	All drain points will have air break	Acceptable	Facility Qualification
Measuring Instruments:										

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55.	Measuring Instruments	Measuring instruments are not in defined range	Yes	Instruments are not suitable for use.	No	NA	High	Measuring ranges shall be defined	Acceptable	IQ / OQ
56.	Measuring Instruments	Measuring instruments could not be calibrated	Yes	Instruments are not suitable for use as it may produce false results	No	NA	High	• Must be calibrated and suitable for recalibration • Suitable calibration certificate shall be provided	Acceptable	IQ / OQ
57.	Pressure of chamber	Pressure of chamber cannot be measured	Yes	GMP requirement	No	NA	Medium	• Provision for measurement of differential pressure • Magnehelic gauge shall be installed to monitor the pressure of chamber • There should be alarm in case pressure reaches out of specification	Acceptable	IQ / OQ

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58.	Differential pressure across the HEPA filter	Differential pressure across the HEPA filter cannot be measured	Yes	GMP requirement	No	NA	Medium	• Differential pressure gauge / magnehelic gauge shall be provisioned to monitor differential pressure across the HEPA • Alarm for pressure out of specification	Acceptable	IQ / OQ
Air filteration										
59.	Air filtration	Air is not filtered / contaminated	Yes	Cross contamination possible , product may get contaminated	No	NA	High	In the supply and exhaust air double HEPA shall be provisioned to ensure pure air	Acceptable	IQ / OQ
60.	HEPA filter	Integrity of HEPA filter cannot be tested	Yes	Basic GMP requirement	No	NA	High	There should be POA/DOP port for integrity testing	Acceptable	IQ / OQ
61.	Coarse filter	Air not filtered from coarse particle	Yes	HEPA filter could functioned properly	No	NA	High	Coarse filter shall be installed before the HEPA filter	Acceptable	IQ / OQ
Environment										

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62.	Power failure	Equipment start after recovery without human intervention	No	Does not have any impact on the quality of the product	EHS	Machine function may get disturbed, may lead to accident	Medium	• On power failure equipment shall come to rest, to protect equipment itself • Power restart must not be automatic and human intervention must be required	Acceptable	IQ / OQ
63.	Closer for rotating parts	Closer not provided to equipment	No	Does not have any impact on the quality of the product	EHS	May leads to accident	High	Appropriate closer for all rating parts in the equipment shall be provided	Acceptable	IQ
64.	Noise level	Too much noise generated by equipment	No	Does not have any impact on the quality of the product	EHS	May cause deafness to the operator/ staff	Medium	Noise level below 80 db at a distance of 1 m from the equipment	Acceptable	OQ
Documentation:										
65.	Documentation	Critical surfaces are not tested for material of construction and test reports are not provided	Yes	Lack of documented evidence leads to question on the quality of MOC	No	NA	High	MOC description and certification of critical parts to be provided	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
66.	Documentation	Instruments are not provided with calibration certificate	Yes	Calibration cannot be assured due to lack of documented evidence	No	NA	High	Critical instrumentation shall be supported with calibration certificates.	Acceptable	IQ / OQ
67.	Documentation	Equipment is not provided with design and functional specification	Yes	Design qualification is not possible	No	NA	High	Design and functional specification should be supplied as per URS	Acceptable	IQ / OQ
68.	Documentation	Equipment is not provided with Operation & maintenance manual	Yes	Correct operation is not ensured and Qualification requirement	No	NA	High	O & M manual should be supplied per URS	Acceptable	IQ / OQ
69.	Standard Operating procedure	Standard operating procedures are not available.	Yes	Procedures critical operations cannot be carried out successfully resulting process failure.	Operational	Productivity will get decrease to unavailabilit y of procedure.	High	SOPs for Operation, Cleaning and maintenance shall be prepared in line with operational and maintenance manual and finalized.	Acceptable	IQ / OQ

9.0 Summary and Conclusion:

- The risk assessment is performed to establish the design parameters of the equipment so as to meet the desired performance of the equipment i.e. Dispensing, Sieving & Blending isolator.
- 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 at the time of accomplishment of OQ of the machine.
- To control the risk, various mitigation methods shall be verified through SOPs ,operation & maintenance manuals, and calibration certificates at respective verification points
- Based on Risk assessment, the URS shall be prepared.

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

10.0 Abbreviation:

Acronym	Definition
cGMP	Current Good Manufacturing Practice
db	Decibel
EU-GMP	European –Good Manufacturing Practice
GA	General Arrangement
GMP	Good Manufacturing Practices
HEPA	High efficiency particulate air
HMI	Human Machine Interface
IQ	Installation Qualification
MOC	Material Of Construction
OQ	Operational Qualification
O & M	Operation and Maintenance Manual
PQ	Performance Qualification
PLC	Programable logic controller
RH	Relative humidity
SOP	Standard Operating Procedures
SS	Stainless steel
URS	User Requirement Specification
w.r.t.	With respect to