Risk Assessment Document
For
Dispensing Booth

RISK ASSESSMENT FOR DISPENSING BOOTH

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RISK ASSESSMENT FOR DISPENSING BOOTH

1 Introduction

According to the definition, given in Annex 15 to the EU-GMP-Guide, a Risk Assessment is a method to assess and characterize the critical parameters in the functionality of an equipment or process. Therefore, risk assessment is a key element in the qualification and validation approach.

In the project context, risk assessment for the equipment is performed as basic GMP/ EHS-Risk Assessment, which shall help to identify important GMP/ EHS-requirements.

2 Aim of Risk Assessment

At the very basic stage of design the Risk Assessment is carried out to verify that all features are taken into consideration to avoid the risk of failure of critical GMP and EHS parameter in the equipment.

During study, all GMP, EHS and operational parameters will be identified and assessed for the risk, appropriate mitigation will be proposed and verification point will be identified and defined.

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

3 Reference Documents/ Drawings

S.No.	Document Title	Document Number
1.	Validation master plan	

4 Equipment/ System Description

The risk assessment is carried out for Dispensing booth consisting of the following main components:

- Supply HEPA filter module
- Return Pre-filter module
- Intermediate filter module
- Main Cabinet
- Light arrangement

Dispensing booth is reverse laminar air flow (RLAF) and designed for ISO 4.8 requirements as per ISO 14644-1. Dispensing booth shall be facilitated with provision for connectivity of weighing balances. Filtration of air is arranged through pre filters (G-4, 15µm), intermediate filter (F-7, 5µm) and terminal HEPA filter (H-14, 0.3µm). The operation is based on VFD control to maintain desired pressure and velocity of air. The equipment is controlled by ON/OFF switches for blower and lights. For light sensitive products provision of sodium vapour lamp shall be provided with separate ON//OFF switch.

In this GMP risk assessment all critical components of the Dispensing Booth, based on the technical details, are listed and rated according to their influence of the product quality, EHS and operational requirements. Most of the possible risk concerning the operation of the Dispensing Booth has been considered in this RA document.

5 Participants

Name	Designation/ Department	Signature/ Date

6 Risk Management Process

A typical Risk management process consists of following steps:

- Risk Assessment:
  - Risk Identification
  - Risk Analysis
  - Risk Evaluation

- Risk Control
  - Risk Reduction
  - Risk Acceptance

- Result of Risk management processes
- Risk Review

- Risk Assessment consists of the identification of hazards and the analysis and evaluation of risks associated with exposure to those hazards.
  Risk identification is a systematic use of information to identify hazards referring to the risk question or problem description.
  Risk analysis is the estimation of the risk associated with the identified hazards. It is the qualitative or quantitative process of linking the likelihood of occurrence and severity of harm.

  Risk evaluation compares the identified and analyzed risk against given risk criteria. Risk evaluation considers the strength of evidence for all three of the fundamental questions.
  The output of a risk assessment is either a quantitative estimate of risk or a qualitative description of range of risk. In case of qualitative description the risk is expressed using descriptors such as “high”, “medium” or “low”.

- Risk control includes decision making to reduce and/ or accept risks. The purpose of risk control is to reduce the risk to an acceptable level. The amount of effort used of risk control should be proportional to the significance of the risk.
  Risk reduction focuses on processes for mitigation or avoidance of quality risk when it exceeds a specified (acceptable) level. Risk reduction might include actions taken to mitigate the severity and probability of harm.
  Risk acceptance is a decision to accept risk. Risk acceptance can be a formal decision to accept the residual risk or it can be a passive decision in which residual risks are not specified.
- The output/ result of the quality risk management process should be appropriately communicated and documented.
- Risk management should be an ongoing part of the quality management process. A mechanism to review or monitor events should be implemented.

- The output/ results of the risk management process should be reviewed to take into account new knowledge and experience.

- Risk management should be an ongoing part of the quality management process. A mechanism to review or monitor events should be implemented.
  The output/ results of the risk management process should be reviewed to take into account new Knowledge and experience.

  This document applies the risk management principles to identify the risks associated with the design, Construction and operational features of the proposed sterile formulation facility.
  The objectives of this risk assessment are to:
  • Review the design around a structured methodology
  • Identify the failure modes and associated risks
  • Check if the proposed control measures are adequate
  • Identify recommendations to obtain a more acceptable risk level if required

6.1 Identifying GMP risk

Identification of Risk associated with the equipment, is generally based on prior experience and the concerns of the participants of risk assessment document.

The risks identified are categorized as “GMP risk” or “Non-GMP risk”.

GMP is defined as “the practices which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.”

Thus, GMP covers all aspects of the manufacturing process: defined manufacturing process; validated critical manufacturing steps; suitable premises, storage, transport; qualified and trained production and quality control personnel; adequate laboratory facilities; approved written procedures and instructions; records to show all steps of defined procedures have been taken; full traceability of a product through batch records and distribution records; and systems for recall and investigation of complaints.

Thus those risks which might have a direct or indirect impact on the quality of the product are classified as “GMP risk”. Also, those risks which might result in regulatory guidelines non-compliance are also classified as “GMP risk”.
For example: The Hygiene level of the manufacturing areas has a direct impact on the quality of the
Product. Thus, it is classified as GMP risk.
The “Non GMP” risks include risks related to EHS, operational and other non-critical hazards.

Following types of risks are mainly identified during risk assessment process:

- Risk related to hygiene level of the manufacturing and supporting areas
- Risks related to appropriate utilities and their control (eg. power source, compressed air etc.)
- Risks related to calibration/ preventive maintenance
- Risks related to protection the environment and health & safety of personnel.
- Risks related to cleaning & sterilization
- Risks related to unidirectional flow of the material

- Risks related to cross contamination of the products
- Risks related to entry and exit of personnel and material.
- Risks related to all the environment features of the manufacturing areas.
- Risks related to requirement of particular rooms for different activities.
- Risks related to environment health and safety of personnel.

6.2 RISK ANALYSIS & EVALUATION

The risk analysis is performed using a qualitative basis of approach.

Qualitative analysis uses word form or descriptive scales to describe the magnitude of potential consequences/ impact and the likelihood that those consequences will occur.

The qualitative measures of likelihood includes descriptors like “Unlikely”, “Possible” and “Likely”, whereas the qualitative measures of consequence/ impact includes descriptors like “Minor”, “Moderate” and “Major”.

Qualitative measures of likelihood

Level	Descriptor	Example detail description
1	Unlikely	May occur at some time
2	Possible	Might occur at some time
3	Likely	Will probably occur in most circumstances

Qualitative measures of consequence/ impact

Level	Descriptor	Example detail description
1	Minor	• No impact on the product quality or outcome of the equipment. • Features required for easing equipment operation.
2	Moderate	• No direct impact on product quality/ outcome of equipment. However may indirectly affect the product quality. • Minor effect on personnel health • Used in the initial stage of operation, however it may affect the final output but those are not used for final release of output. • Effect on environment such as clean room.
3	Major	• Features having direct impact on product quality/ outcome of equipment like contact parts MOC, Surface finish, Control system, Process air quality etc. • Failure could lead to regulatory non-compliance. • Loss/ damage to equipment or its critical sub-components • Critical instruments not calibrated or not of desired range or accuracy. • Proper supporting documentation not provided. • Major effect on personnel health

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

Qualitative risk analysis matrix – level of risk

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

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

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

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

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

7 Risk Assessment

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

Column 1 : **Serial number** of the Risk assessment item

Column 2 : **Process step/ Component**: Identify the process step or component associated with the risk.

Column 3 : **Risks:** Identify the type of risk associated with the process or component

Column 4 : Verify that whether risk have **GMP impact** in terms of Yes/ No.

Column 5 : **Justification:** Provide justification for declaring both Yes/ No for GMP impact in column 4.

Column 6 : For the risk **other than of GMP impact**, write that what is/ are the type of risks e.g. EHS, operational, etc.

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

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

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

Column 9a : **Mitigation Method:** Write the risk mitigation strategy as considered in the design.

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Column 9b	:	**Residual risk level:** After the risk mitigation what is the residual risk level, whether it is Acceptable, Low or Medium.
Column 9c	:	**Test document:** Write the test point where the risk mitigation strategy will be verified.
Column 10	:	**Status of RA:** Mention the status of the Risk assessment point i.e. whether it is ‘Closed” or “Open”, after the execution/ approval of the Test document.

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								Mitigation Method (9a)	Residual risk level (9b)	Verification (9c)	
Process											
1.	Material Dispensing	Insufficient space for accommodating the material dispensing containers and the balance	Yes	Adequate space for the operation is a GMP requirement to conduct error free operation.	Operational	Difficulty in dispensing activity.	Medium	The size of the booth shall be adequate for accommodating the dispensing containers, dispensing material and dispensing balance.	Acceptable	IQ	
2.	Material Dispensing	Powder material spreading in the room out of the booth during the dispensing activity	Yes	Difficult for room cleaning. Potential of cross contamination	EHS	The powder material may be harmful to the operator	High	The dispensing booth shall be reverse flow type LAF with the suction at the bottom sides so that random movement of the particles will be restricted and powder will not be spread out of the booth.	Acceptable	IQ & OQ	
3.	Material Dispensing	Dispensing of material not carried out under ISO 4.8 environment.	Yes	Can lead to contamination of material being dispensed.	No	No	High	HEPA filter (efficiency 99.997%) should be installed at the terminal so as to deliver clean air during dispensing.	Acceptable	IQ	
4.	Return air	Failure of the laminarity due to the resistance in return air	Yes	Due to disturbance of air flow, air become turbulent and powder can spread outside the booth.	No	NA	High	Return filter size should be of appropriate grade/size for smooth return of air.	Acceptable	OQ	

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5.	Return air	Return air recirculating and coming out from the dispensing booth inside the room is contaminated with powder.	Yes	Potential of cross contamination	EHS	Product exposure	High	The return air shall be filtered through a series of filter as pre-filter, intermediate filter 5µm) and final filter (0.3µm) HEPA filter.	Acceptable	IQ	
6.	Lighting	No or insufficient light inside the booth	Yes	Visibility for critical operation is a GMP requirement	Operational	No light may lead to difficulty during the dispensing activity	Medium	• Fluorescent light shall be provided for adequate visibility with ON/OFF switch. • Adequate level of light (lux level >400) shall be provided in working place	Acceptable	IQ & OQ	
7.	Light sensitive products	No provision for dispensing of light sensitive products	Yes	Light sensitive products may be degraded while dispensing in normal light.	No	NA	High	Provision for sodium vapour lamp shall be provided with separate ON/ OFF switches for dispensing of light sensitive products.	Acceptable	IQ	
8.	Blower running	Continuous running of the blower	No	No impact on the product	Operational	Continuous running of the blower shall cause lot of power loss and may damage the blower	Medium	• The ON/OFF switch shall be provided for controlling the blower operation. • LED indicators for the motor operation shall be provided.	Acceptable	IQ	

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9.	Hygiene zone	Area under Dispensing booth does not meet specified hygiene class parameters.	Yes	Equipment will not be suitable for operation.	No	NA	High	• Qualification of the equipment hygiene class is to be done. • Area cleaning and monitoring is to be done.	Acceptable	OQ, PQ & SOP	
10.	Air flow	• Abnormal flow rate of the air. • The air flow is not laminar.	Yes	Loss of laminarity and will lead to turbulence of the air leading to increase in particulate matter	Operational	High flow rate leads to HEPA filter damage	High	• The air velocity shall be controlled by VFD and dampers to maintain the required CFM at working level for uniform laminarity. • The velocity of the air through HEPA filter should be controlled and set at 90 fpm ± 20%. • PVC curtains are to be provided for ensuring laminarity of air. • Vendor shall demonstrate laminar air flow at the working level.	Acceptable	IQ & OQ	
11.	HEPA filter	Supply HEPA filter choked during routine operation	Yes	The required flow for the laminarity may not be achieved	No	NA	High	• Pre-filter and Intermediate filter to be placed before HEPA filter. • Magnehelic gauge to measure and indicate the differential pressure across HEPA shall be provided.	Acceptable	IQ	
12.	Pre-filters and Intermediate filter	Choking or leakage of Pre-filter and intermediate filter	Yes	The required flow for the laminarity may not be achieved.	No	NA	high	Magnehelic gauges to measure and indicate the differential pressure across pre-filters and intermediate filters shall be provided.	Acceptable	IQ	

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13.	Air Supply	Non-Integrated HEPA filters	Yes	Filter efficiency inadequate to the standards.	No	NA	High	Provision of a port for monitoring upstream PAO concentration at the time of integrity testing of the filters.	Acceptable	IQ	
14.	Air Supply	Failure of Filters	Yes	Admission of contaminated air in to the dispensing booth.	No	NA	High	• Filter Integrity Test to be carried-out regularly. • SOP: Requalification of Dispensing booth to include integrity testing of HEPA filter.	Acceptable	OQ & SOP	
15.	Recovery time	Immediate dispensing activity just after start up	Yes	There are chances of improper removal of initial particle contamination from the inside work area. This may lead to contamination of the product from the air	No	NA	High	Before the dispensing activity is to be taken the equipment shall allowed to be run continuously for a set period of time. The limit shall be established during qualification.	Acceptable	PQ & SOP	
16.	Joint sealing	Joints are not sealed	Yes	It will allow accumulation of powder which may lead to contamination.	No	NA	High	Proper sealing over the joints shall be provided	Acceptable	IQ	
17.	Safe working zone	Safe working zone is not defined	Yes	Area for laminar air flow cannot be identified which is required for containment.	No	NA	Medium	Safe working zone shall be marked and this will be verified in further qualification.	Acceptable	PQ	
18.	HEPA filter placement	Chance of dead space if HEPA filters not placed properly.	Yes	Laminar air flow may get disturbed.	No	NA	Medium	Proper placement of HEPA filter should be considered to attain minimum dead space.	Acceptable	IQ & OQ	

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19.	Connection of instruments	No provision for connection of weighing balance inside dispensing booth.	No	No impact on product quality	Operational	Separate power socket has to be provided from external points.	Low	Single phase 3 pin power sockets are to be provided inside dispensing booth for connection of at least 2 weighing balances.	Acceptable	IQ	
Cleaning and Material of Construction											
20.	Cleaning	Cleaning of the pre-filters & intermediate filters not possible	Yes	The required flow of air cannot be achieved due to choking of the pre-filters or intermediate filter.	Operational	Frequent changes of the pre-filters shall be required	High	The pre-filters and intermediate filters used at the return shall be detached easily and shall be cleaned easily.	Acceptable	IQ	
21.	Cleaning	Dispensing booth is not cleanable.	Yes	May cause contamination of product.	No	NA	Medium	• Smooth surface, no crevices, accessibility for cleaning. • All bolts, nuts on the exterior part of equipment will be with cap head or cap nut.	Acceptable	IQ	
22.	Welding joints	Weld joints not ground properly	Yes	Uneven and improperly ground weld joints will form a space for dust accumulation.	No	NA	Medium	All welds shall be grounded to smooth finish.	Acceptable	IQ	
23.	Material	The surface is not compatible with the decontaminating agents	Yes	Contamination	No	NA	Medium	All metallic contact surfaces shall be constructed of 316 or better grade stainless steel.	Acceptable	IQ	

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24.	Polymeric material	Polymeric materials are not compatible and are not replaceable		Shall lead to contamination or leakages	No	NA	High	• Polymeric material shall be made up of food grade materials only. • The easy change of gaskets must be possible. • Vendor shall provide the certificate for food grade polymeric material.	Acceptable	IQ	
25.	Finishing	External finish is not proper.	Yes	May lead to improper cleaning of the surface which will lead to	No	NA	Medium	All external surface finish shall be smooth finish	Acceptable	IQ	
26.	Labelling	Labelling of components inappropriate.	Yes	Prerequisite for qualification	No	NA	High	• Unique identity no. / flow direction must be on components / media, operator panel, etc. (e.g. according to GA/ P&ID). • All labelling in English language and according to project standard.	Acceptable	IQ	
Maintenance											
27.	Filter removal	The removal filters is not possible	Yes	Pre-filters needs to be regularly cleaned. Intermediate filter & HEPA filters needs to be replaced in case of any damage.	No	NA	High	• The equipment should have access panel for easy servicing or removal of intermediate filter and HEPA filter. • Pre-filter should be of detachable type and easily cleanable.	Acceptable	IQ	

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28.	Maintenance	Malfunctions due to worn parts	Yes	Basic GMP requirement	No	NA	Medium	• Machine shall be easy to maintain. • Preventive maintenance procedure should be available • The unit must contain necessary protection devices to ensure that the equipment & the article remain in a safe condition.	Acceptable	IQ & SOP	
29.	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											
30.	HEPA filters, pre-filter and electrical sockets	During cleaning HEPA filter, pre-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. • Protective grills for HEPA and Pre-filter. • Safety instruction on the conductive surface/ area for not using cleaning agents.	Acceptable	IQ	
31.	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	OQ	
32.	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	Medium	Noise level shall be below 75 db at a distance of 1 m from the equipment.	Acceptable	OQ	

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33.	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	
Measuring Instrument											
34.	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 & OQ	
35.	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	
36.	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	
Documentation											
37.	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, trouble shooting & maintenance related activities.	Acceptable	OQ & SOP	

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38.	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	
39.	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 sheets • Material certificates & surface finish reports • O&M manual • Calibration certificates • Parts list (sufficient details - part no., supplier, type etc.) • Drawings (GA, Power wiring etc.). • Certificates of bought out components. • Filter certificates	Acceptable	IQ	

8 Summary & Conclusion

- The Risk Assessment was performed to establish the design parameters of the equipment so as to meet the desired performance of the equipment i.e. Dispensing Booth.
- The critical risks pertained to GMP and other than GMP, were analyzed with justification and mitigation procedures.
- For each recognized GMP-risk and other than GMP risks, necessary measures are defined. Organizational measures, like SOPs, are also possible measures for special GMP-risks. The availability of these SOPs will be checked during the performance of the OQ.
- The risks where conceptual procedures shall be employed, standard operating procedures (SOPs), Preventive maintenance schedules, Certificates and related documents indicated as mitigation procedures shall be ensured at respective test points

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

9 Abbreviations

EU-GMP	:	European – Good Manufacturing Practice
EHS	:	Environment Health Safety
GMP	:	Good Manufacturing Practice
HEPA	:	High Efficiency Particulate Air
DP	:	Differential Pressure
PAO	:	Poly Alfa Olefin
VFD	:	Variable Frequency Drive
LED	:	Light Emission Diode
PVC	:	Poly Vinyl Chloride
GA	:	General Arrangement
P&ID	:	Piping & Instrumentation Diagram
NMT	:	Not More Than
SOP	:	Standard Operating Procedure
SS	:	Stainless Steel
UPS	:	Uninterrupted Power Supply
db	:	Decibel
FS	:	Functional Specification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PQ	:	Performance Qualification
O&M	:	Operation and Maintenance
GA	:	General Arrangement
IPSI	:	Integrated Project Services International, New Delhi

10 Revision History

Date	Revision	Reason for Revision
	00	New Document