RISK ASSESSMENT FOR DISPENSING BOOTH

Risk Assessment For

Dispensing Booth

Equipment/System ID:- ……

RISK ASSESSMENT FOR DISPENSING BOOTH

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1.0 Approval Signature

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

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

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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 characterise the critical parameters in the functionality of an equipment or process. Therefore, risk assessment is a key element in the qualification and validation approach.

In the project context, risk analyses are performed as basic GMP/EHS-Risk assessment, which shall help to identify important GMP/EHS-requirements.

3.0 Aim of the Risk Analysis

At the very basic stage of design the risk assessment is to verify that all features are taken into consideration to avoid the risk of failure of critical GMP and EHS parameter in the equipment.
During study all GMP and EHS parameters will be identified and assessed for the risk if not considered in the design or requirements.
The Risk assessment report is produced to provide the documented evidence that design concepts or requirement are complete in considering all GMP and EHS risks.

4.0 Reference Documents

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

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5.0 System Description

The Dispensing booth shall be used to dispense the Raw materials under reverse laminar airflow. The reverse laminar airflow booth shall be facilitated with provision for connectivity of weighing balances. Magnehelic gauge shall be provided to monitor the differential pressure and Air flow velocity sensor shall be provided to maintain the air velocity. Suitable light system shall be provided to get maximum illumination.

6.0 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 (e.g. Selection of SS grade, gaskets, lubricants etc.)
- Risks related to appropriate utilities and their control (e.g. 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".

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Qualitative measures of likelihood

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

Qualitative measures of consequence/ impact

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

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

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Qualitative risk analysis matrix – level of risk

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

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

Low Risk can be Acceptable 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.

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7.0 Risk Assessment

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 4.
Column 6:	**GMP Risk:** For the risk **other than of GMP impact,** write what is the type of risks e.g. EHS, Operational.
Column 7:	**Justification**: Provide justification for considering any risk.
Column 8:	**Risk level** Determine the Risk level as High, Medium or low based on the impact.
Column 9:	**Risk Control:** It is further divided into following three sections
Column 9a:	**Mitigation Method**: Write the risk mitigation strategy as considered in design.
Column 9b:	**Residual risk level**: After the risk mitigation what is the residual risk level, whether it is acceptable, low or Medium
Column 9c:	**Verification**: Write the test point where the risk mitigation strategy will be verified.

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								Mitigation Method (9a)	Residual Risk Level (9b)	Verification (9c)
A.	**Design:**									
1.	Working Space	Insufficient space for performing the activity	Yes	Adequate space for the operation is a basic GMP requirement	Operational	Difficult to perform activity	Medium	The working space of LAF unit shall be adequate for performing the relevant activity.	Acceptable	IQ
2.	Clean-ability	Contamination of Clean-rooms	Yes	Surface of the equipment may encourage dust accumulation/ microbial growth	No	NA	High	The design must ensure easy clean-ability by providing smooth surface finishes and round edges	Acceptable	IQ/OQ

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B. Process										
3.	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	Product exposure	High	The dispensing booth shall be Reverse Laminar Air Flow type (Flame proof) so that random movement of the particles shall be restricted and powder shall not spread out of the booth.	Acceptable	IQ/OQ
4.	Material Dispensing	Dispensing of material not carried out under Grade A environment.	Yes	The Viable and non-viable particles may contaminate the dispensed material	No	NA	High	• The air must be filtered through the terminal HEPA filter • Grade A should be qualify during OQ.	Acceptable	IQ/OQ

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5.	Exhaust of air	Non laminarity of air from LAF due to improper exhaust of air from the booth.	Yes	Due to disturbance of LAF, air become turbulent and powder can spread outside the booth	EHS	Material exposure may contaminate the surrounding area and may have adverse effect on operators health	High	Return filter (05µ) should be provided	Acceptable	IQ/ OQ
6.	Exhaust of air	Exhaust air coming out of the room is contaminated with powder	Yes	Potential of cross contamination.	EHS	Product exposure to the environment	High	The exhaust of air shall be through series of filter as Pre filter 5 µ, intermediate 3µ and final filter 0.3µ HEPA filters.	Acceptable	IQ/OQ

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7.	Lighting	Inadequate light inside the booth	Yes	Visibility for critical operation is GMP requirement	Operational	No light may lead to difficulty during the dispensing activity.	Medium	400 lux level light should be provided for proper visibility.	Acceptable	IQ/OQ
8.	UV light	Increased bio-burden	Yes	Chances of material contamination	No	NA	High	UV Light with digital hour meter shall be provided.	Acceptable	IQ/OQ
9.	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.	Acceptable	IQ
10.	vibration of blower	Abnormal vibration of Blower	Yes	Spillage of product	Operational	Operator cannot perform his operations well.		Anti vibration pads or suitable mechanism shall be provided.	Acceptable	IQ/OQ

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11.	hygiene Zone	Area under Dispensing booth does not meet specified hygiene class parameters.	Yes	Equipment will not be suitable for operation. Chances of product contamination during dispensing.	No	NA	High	• Qualification of the equipment for hygiene class specifications is to be done. • Area cleaning and monitoring duration shall be considered in EM SOP.	Acceptable	OQ/ PQ/ SOP

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12.	Air flow	Abnormal flow rate of the air The Air flow is not laminar	Yes	Loss of laminarity and may lead to turbulence of the air.	EHS	Material exposure may contaminate the surrounding area and may have adverse effect on operators health	High	The flow rate shall be controlled to maintain the laminarity of air.	Acceptable	OQ

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13.	HEPA Filter	Supply HEPA filter choked during the routine operation	Yes	The required flow for the laminarity may not be achieved.	No	NA	High	• Pre and intermediate filters shall be consider to protect HEPA filter • Differential pressure across the HEPA filter shall be monitored continuously and indicated. • Magnehelic Gauge should be provided.	Acceptable	IQ/OQ

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14.	pre filter 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
15.	HEPA filter	No provision for carrying out the integrity test for the HEPA filters	Yes	The integrity test of the HEPA filters is essential requirement to confirm the proper functioning of the HEPA filter	No	NA	High	The port for monitoring of upstream concentration of PAO shall be provided in the equipment.	Acceptable	IQ/OQ

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16.	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 periodically SOP shall be defined	acceptable	OQ/ SOP

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17.	Activity after immediate start up	Immediate dispensing activity just after equipment start up without recovery of desired conditions	Yes	There are chances of improper removal of initial particle from the dispensing area. This may lead to cross contamination.	No	NA	High	• Before the dispensing activity to be taken the equipment shall be allowed to run continuously for a set time period. • The limit shall be established during the qualification. • The initial recovery time shall be monitored and the completion time shall be indicated by Alarm.	Acceptable	OQ

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18.	joints sealing	inadequate joint sealing	Yes	accumulation of powder may lead to contamination	No	NA	high	Proper sealing over the joints shall be provided	acceptable	IQ
C. Cleaning & Material of Construction:										
19.	Cleaning	Cleaning of the pre filters not possible	Yes	The required flow of air cannot be achieved due to chocking of the pre filters	Operational	Product contamination	High	Frequent changes of the pre filters shall be required. The pre filters at the return (5µ) used shall be detachable and cleanable	Acceptable	OQ
20.	Cleaning	Cleaning of external part not possible	Yes	Cleaning is basic GMP requirement	No	NA	Medium	The external part of the equipment shall be designed for manual cleaning	Acceptable	IQ

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21.	MOC	The surface is not compatible with the clean room	Yes	May lead to the product and environment contamination	No	NA	High	All metallic non product contact surfaces shall be constructed of 304 grade stainless steel or better. Electrical switch/ sockets shall be provided with SS cladding.	Acceptable	IQ

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22.	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
23.	Finishing	External finish is not proper	Yes	May lead to improper cleaning of the surface which will lead to contamination	No	NA	Medium	All external surface finish shall be smooth finish	Acceptable	IQ

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24.	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
D. Safety:										

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25.	Power Failure	Power failure during activity	Yes	Can lead to contamination of the material being dispensed/ sampled or the clean room	EHS	Safety requirement	area contamination	On power failure equipment should come in fail safe condition & on recovery of the power failure the equipment shall retain the normal condition. • UPS supply should be provided for continuous operation.	Acceptable	OQ

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26.	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 80 db at a distance of 1 m from the equipment	Acceptable	OQ
27.	Earthing	Improper earthing may lead to electric shock	No	No impact on product quality	EHS	Accident may take place due to generation of static charge	High	Proper earthing shall be considered in the design	Acceptable	IQ

E. Measuring Instruments:

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28.	Measuring Instruments	Measuring instruments are not within defined range and accuracy	Yes	Improper monitoring of Process parameters	No	NA	High	Measuring Instruments must have a suitable measuring range. Measuring Instruments must have appropriate accuracy.	Acceptable	IQ/OQ
29.	Measuring Instruments	Measuring instruments could not be calibrated	Yes	Instruments are not suitable for calibration.	No	NA	High	Must be calibrated and suitable for calibration	Acceptable	IQ/OQ

F. Documentation:

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30.	Documentation	Critical surfaces are not tested for MOC and test reports are not provided	Yes	Lack of documented evidence	No	NA		Material test certificate, Welding certificates, lubricant food grade certificates shall be provided. Guaranty/Warranty certificates shall be provided.	Acceptable	IQ/OQ
31.	Documentation	Filter integrity test certificates are not provided	Yes	Lack of documented evidence	No	NA		Filter integrity test certificates must be provided	Acceptable	IQ

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32.	Documentation	Instruments are not provided with calibration certificate	Yes	Lack of documented evidence	No	NA		Calibration certificate shall be provided	Acceptable	IQ/OQ

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33.	Documentation	Equipments is not provided with design and functional specification	Yes	Qualification requirement	No	NA		• Functional and design specification • Spare part lists • Final as built diagram • GA-diagrams • Electrical diagrams • Functional design specification • All qualification documents • Drawings shall be provided	Acceptable	IQ/OQ

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34.	Documentation	Equipment is not provided with operation and maintenance manual	Yes	Operational requirement	No	NA	Yes	Operation and maintenance manual, preventive maintenance instruction & schedule for equipment major component as well as the operating system. Control system operation manual shall be provided. Installation instructions shall be provided.	Acceptable	IQ/OQ

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35.	Standard Operating procedure	Standard operating procedures are not available	Yes	In lack of standard operating procedures critical operations cannot be carried out successfully resulting in process failure.	Operational	Productivity may be reduced due to unavailability of procedure.		SOPs for Operation, Cleaning and maintenance, Trainings shall be prepared in line with operational and maintenance manual and finalized.	Acceptable	OQ

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36.	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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37.	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. •	Acceptable	IQ

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S. No (1)	Process steps/ component (2)	Risk (3)	GMP Risk Yes/No (4)	Justification (5)	Other Risk type (6)	Justification (7)	Risk Level (8)	Risk control		
								Mitigation Method (9a)	Residual Risk Level (9b)	Verification (9c)

RISK ASSESSMENT FOR DISPENSING BOOTH

8.0 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. Dispensing Booth.
- 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 analysis** performed for the equipment will prevent the risk of failures of critical parameters during design, commissioning, installation, operation and performance of the equipment".*

9.0 Abbreviations and Definitions

Acronym	Definition
GMP	Good manufacturing practices
EHS	Environment health and safety
IQ	Installation Qualification
DQ	Design Qualification
OQ	Operational Qualification
PQ	Performance Qualification
UV	Ultra Violet
MOC	Material of construction
HEPA	High Efficiency Particulate Air
DIB	Dispensing Booth
db	Decibel
GA	General arrangement
SOP	Standard Operating Procedure
MOC	Material Of Construction