Risk Assessment Document for Dispensing Booth	
Identification No.:	**Document Number:**
Effective Date:	**Revision No.:** 00

Risk Assessment Document

Dispensing Booth

Equipment ID: ……

Revision index

Revision	Date	Reason for revision
00		First issue

Risk Assessment Document for Dispensing Booth	
Identification No.:	**Document Number:**
Effective Date:	**Revision No.:** 00

Table of Contents

Risk Assessment Document for Dispensing Booth	
Identification No.:	**Document Number:**
Effective Date:	**Revision No.:** 00

1.0 Approval signature:

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/Warehouse		
Engineering		
Quality Assurance		

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

Risk Assessment Document for Dispensing Booth	
Identification No.:	**Document Number:**
Effective Date:	**Revision No.:** 00

2.0 Introduction:

According to the definition, given in Annex 15, 20 to the EU-GMP-Guide & ICH Q9 – Quality Risk management, a risk assessment is a method to assess and characterise the critical parameters in the functionality of an equipment or process. Therefore, risk assessments are a key element in the qualification and validation approach.

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

3.0 Aim of the Risk Analysis:

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

During study all GMP and EHS parameters will be identified and assessed for the risk if not considered in the design or requirements.

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

4.0 Reference Documents:

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

Risk Assessment Document for Dispensing Booth	
Identification No.:	**Document Number:**
Effective Date:	**Revision No.:** 00

5.0 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
- Microvee filter module
- Main Cabinet
- Light arrangement

Dispensing booth is used to perform dispensing/sampling operations in pharmaceutical industries. The equipments serve as safety equipment to operator doing the dispensing operation. In dispensing from big packing of dangers chemicals converted to small packing by operator under class 100 environments and 10% exhaust system is adopted. Dispensing unit is always negative pressure unit and in equipment air is circulated from outside to inside of the equipment. Hence during dispensing operation powder is always sucked at pre filter given at the bottom of the cabinet. Operators are not affected by the chemicals.

Dispensing booth consists of HEPA filter, micro filter, pre filter and exhaust HEPA filter, with efficiency of 99.997% down to 0.3µ at rated air flow and pressure drop 12 mm is adjusted to get laminar flow in the equipment. HEPA filter made up of imported glass fiber media as high final pressure drop for long lasting environmental clean level.

System is equipped with inbuilt motor blower dynamically balanced for low noise and vibration. Micro filter and pre filter at suction 10% air is discharged through exhaust HEPA filter to generate negative pressure in equipment.

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.

6.0 Participants:

Name	Function	Signature

7.0 Risk Management Process:

A typical Risk management process consists of following steps:

- Risk Assessment:
  - Risk Identification
  - Risk Analysis
  - Risk Evaluation
- Risk Control
  - Risk Reduction
  - Risk Acceptance
- Result of Risk management processes
- Risk Review
- **Risk Assessment:**

  It consists of the identification of hazards and the analysis and evaluation of risks associated with exposure to those hazards.
  Risk identification is a systematic use of information to identify hazards referring to the risk question or problem description.
  Risk analysis is the estimation of the risk associated with the identified hazards. It is the qualitative or quantitative process of linking the likelihood of occurrence and severity of harm.
  Risk evaluation compares the identified and analyzed risk against given risk criteria. Risk evaluation considers the strength of evidence for all three of the fundamental questions.
  The output of a risk assessment is either a quantitative estimate of risk or a qualitative description of range of risk. In case of qualitative description the risk is expressed using descriptors such as “high”, “medium” or “low”.

- **Risk control:**

  It includes decision making to reduce and/ or accept risks. The purpose of risk control is to reduce the risk to an acceptable level. The amount of effort used of risk control should be proportional to the significance of the risk.
  Risk reduction focuses on processes for mitigation or avoidance of quality risk when it exceeds a specified (acceptable) level. Risk reduction might include actions taken to mitigate the severity and probability of harm.
  Risk acceptance is a decision to accept risk. Risk acceptance can be a formal decision to accept the residual risk or it can be a passive decision in which residual risks are not specified.

- The output/ result of the quality risk management process should be appropriately communicated and documented.
- Risk management should be an ongoing part of the quality management process. A mechanism to review or monitor events should be implemented.

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

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

7.1 Identifying GMP risk:

Identification of Risk associated with the equipment, is generally based on prior experience and the concerns of the participants of risk assessment document.
The risks identified are categorized as "GMP risk" or "Non-GMP risk".
GMP is defined as "the practices which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization."
Thus, GMP covers all aspects of the manufacturing process: defined manufacturing process; validated critical manufacturing steps; suitable premises, storage, transport; qualified and trained production and quality control personnel; adequate laboratory facilities; approved written procedures and instructions; records to show all steps of defined procedures have been taken; full traceability of a product through batch records and distribution records; and systems for recall and investigation of complaints.

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

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

- Risk related to product contact materials for equipment and containers (eg. Selection of SS grade, gaskets, lubricants etc.)
- Risks related to appropriate utilities and their control (eg. Steam, gases, power source, compressed air etc.)
- Risks related to calibration/ preventive maintenance
- Risks related to protection the environment and health & safety of personnel.
- Risks related to cleaning & sterilization
- Risks related to control system of the equipment
- Risks related to product loss

7.2 Risk Analysis & Evaluation:

The risk analysis is performed using a qualitative basis of approach.
Qualitative analysis uses word form or descriptive scales to describe the magnitude of potential consequences/ impact and the likelihood that those consequences will occur.
The qualitative measures of likelihood includes descriptors like "Unlikely", "Possible" and "Likely", whereas the qualitative measures of consequence/ impact includes descriptors like "Minor", "Moderate" and "Major".

Qualitative measures of likelihood

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

Risk Assessment Document for Dispensing Booth	
Identification No.:	**Document Number:**
Effective Date:	**Revision No.:** 00

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.

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

Risk Assessment Document for Dispensing Booth

Identification No.:	**Document Number:**
Effective Date:	**Revision No.:** 00

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)
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 weighing 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 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 (10 micron).	Acceptable	IQ

Risk Assessment Document for Dispensing Booth

Identification No.:	**Document Number:**
Effective Date:	**Revision No.:** 00

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)
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 (10µm), microvee 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.	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

Risk Assessment Document for Dispensing Booth

Identification No.:	**Document Number:**
Effective Date:	**Revision No.:** 00

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)
8.	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. • SOP: Cleaning and monitoring of the equipment.	Acceptable	PQ/SOP
9.	UV Light	UV Light not present	Yes	Required for surface sterilization of articles while dispensing of material.	No	NA	High	• UV light should be provided for surface sterilization of articles. • UV light should be provided with ON/ OFF switch.	Acceptable	IQ & OQ
10.	UV light not efficient	Failure of UV light or drop in intensity could not be detected	Yes	UV light may not be efficient after the burning hour	No	NA	High	• An hour meter/ Intensity monitor should be provided for recording burning hour of UV light. • COA for UV light burning hour should be supplied by supplier.	Acceptable	IQ

Risk Assessment Document for Dispensing Booth

Identification No.:	**Document Number:**
Effective Date:	**Revision No.:** 00

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		
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11.	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	• Provision for controlling the air flow to maintain the required Velocity. • 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
12.	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 Microvee filter to be placed before HEPA filter. • Magnahelic gauge to measure and indicate the differential pressure across HEPA shall be provided.	Acceptable	IQ
13.	Pre-filters and microvee filter	Choking or leakage of Pre-filter and Microvee filter	Yes	The required flow for the laminarity may not be achieved.	No	NA	high	Magnahelic gauges to measure and indicate the differential pressure across pre-filters shall be provided.	Acceptable	IQ

Risk Assessment Document for Dispensing Booth

Identification No.:	**Document Number:**
Effective Date:	**Revision No.:** 00

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		
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14.	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
15.	Air Supply	Failure of Filters	Yes	Admission of contaminated air in to the dispensing booth.	No	NA	High	• Filter Integrity Test to be performed during qualification. • SOP: Filter Integrity Test to be carried-out regularly for HEPA filter of Dispensing booth.	Acceptable	OQ & 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 with silicon sealant.	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	OQ/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

Risk Assessment Document for Dispensing Booth

Identification No.:	**Document Number:**
Effective Date:	**Revision No.:** 00

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)
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 atleast 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 microvee filters used at the return shall be detached easily and shall be cleaned easily. SOP: Precaution to be taken during cleaning of filters.	Acceptable	IQ & SOP
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. • SOP: Cleaning of Dispensing Booth.	Acceptable	IQ& SOP

Risk Assessment Document for Dispensing Booth

Identification No.:	**Document Number:**
Effective Date:	**Revision No.:** 00

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		
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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 304 or better grade stainless steel.	Acceptable	IQ
24.	Polymeric material	Polymeric materials are not compatible and are not replaceable	Yes	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 contamination	No	NA	Medium	All external surface finish shall be smooth finish	Acceptable	IQ

Risk Assessment Document for Dispensing Booth

Identification No.:	**Document Number:**
Effective Date:	**Revision No.:** 00

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		
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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

Risk Assessment Document for Dispensing Booth

Identification No.:	**Document Number:**
Effective Date:	**Revision No.:** 00

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		
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28.	Maintenance	Malfunctions due to worn parts	Yes	Basic GMP requirement	No	NA	Medium	• Machine shall be easy to maintain. • The unit must contain necessary protection devices to ensure that the equipment & the article remain in a safe condition. • SOP: Preventive maintenance procedure for the equipment should be available.	Acceptable	IQ & SOP
Safety										
29.	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	• Protective grills for Pre-filter. • Safety instruction on the conductive surface/ area for not using cleaning agents.	Acceptable	IQ

Risk Assessment Document for Dispensing Booth

Identification No.:	**Document Number:**
Effective Date:	**Revision No.:** 00

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		
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30.	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
31.	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
32.	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 Instruments										
33.	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

Risk Assessment Document for Dispensing Booth

Identification No.:	**Document Number:**
Effective Date:	**Revision No.:** 00

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		
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34.	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
35.	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										
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, troubleshooting & maintenance related activities.	Acceptable	OQ&PQ SOP

Risk Assessment Document for Dispensing Booth

Identification No.:	**Document Number:**
Effective Date:	**Revision No.:** 00

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		
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37.	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
38.	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

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. 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".*

10.0 Abbreviations:

Acronym	Definition
cGMP	Current Good Manufacturing Practice
db	Decibel
DIB	Dispensing Booth
DQ	Design Qualification
EHS	Environment Health Safety
EU-GMP	European – Good Manufacturing Practice
FPM	Feet per minute
GA	General Arrangement
GMP	Good Manufacturing Practices
HEPA	High Efficiency Particulate Air
ICH	International Committee for Harmonization
IQ	Installation Qualification

Acronym	Definition
ISO	International Organization for Standardization
LED	Light Emitting Diode
MOC	Material Of Construction
O & M	Operation and Maintenance Manual
OQ	Operational Qualification
PAO	Poly-alpha olefin
P & ID	Piping & Instrumentation Design
PQ	Performance Qualification
PVC	Poly Vinyl Chloride
PVP	Project Validation Plan
QA	Quality Assurance
RLAF	Reverse Laminar Air Flow
SOP	Standard Operating Procedures
SS	Stainless steel
UPS	Uninterrupted Power Supply
URS	User Requirement Specification
VFD	Variable Frequency Drive
VMP	Validation Mater Plan