Risk Assessment
for
Fluid Bed Dryer (30 Kg)
Equipment ID:

Revision index

Revision	Date	Reason for revision
00		First issue

FAILURE MODE EFFECT ANALYSIS FOR FLUID BED DRYER

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1.0 Approval:

This document is prepared by ……..the project "OSD Formulation facility" at ……..under the authority of their Project Manager. Hence, this document before being effective shall be approved by the QA team of …….

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

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

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

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2.0 Introduction:

According to the definition, given in Annex 15, 20 to the EU-GMP-Guide and ICH Q9, a risk Assessment is a method to assess and characterize the critical parameters in the functionality of an equipment or process. Therefore, risk Assessment is a key element in the qualification and validation approach.

In the project context, risk 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:

Construction: Fluid Bed Dryer is used for Rapid and efficient drying of wet granulation, mass granulation of powders. The purpose of Fluid Bed Dryer is to put substances in powdery form (bulk materials) into a suspended state. The fluidizing air in this equipment will enable a very efficient heat and mass transfer (heating, cooling, and drying).

Complete machine can be divided in following sub sections:

- Inlet Air handling Unit (AHU).
- Exhaust Air Blower.
- Machine Tower. (Bottom Chamber, Product Container & Main body)

Principle:- A fluidized bed is formed when an upward flow of process airlifts small particles. As a result, the small particles move rapidly within the fluidized bed and get efficient heat and material exchange between the bed and the fluidizing air. The temperature in the fluidized bed is kept constant across the whole height of the bed to ensure consistent uniform drying.

In this GMP risk Assessment all critical components of the Fluid Bed Drier, 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 (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.

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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".

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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.

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 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.

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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
1.	Loading of material	Product exposure during transfer	No	NA	EHS	Health hazard to the person in contact of the product	Medium	• Loading of material shall be done manually. • Operator shall wear the PPE to avoid the contact with product. • Suitable protective measure should be mentioned in the SOP	Acceptable	SOP Control
2.	Inlet Air	Inlet Air is not filtered	Yes	It will lead to product contamination	No	NA	High	• Proper filtration shall be provided for inlet air. • Pre- filter and final filter shall be installed to ensure adequate filtration of air. • Air Filter assembly with HEPA filter shall be provided. • HEPA filter integrity testing shall be done. • Differential pressure indicator will be considered in the design.	Acceptable	IQ
3.	Inlet air	Uncontrolled Airflow & temperature	Yes	Inlet air flow & temperature control is process requirement	No	NA	High	• Air flow of the inlet air shall be defined. • Temperature shall be controlled and monitor through temperature controller.	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
Process										
4.	Product bowl	Bowl cannot be docked gastight with upper body.	Yes	Area contamination with the product	EHS/ Operational	Product exposure to the personnel. Product loss	High	Inflatable gaskets will be considered for container seal with alarm in case of failure.	Acceptable	IQ & OQ
5.	Product Screen	Product screen is not replaceable in case of damage	Yes	May affect the fluidization process	No	NA	High	Replaceable screens to be considered	Acceptable	IQ
6.	Broken bag detector	Air outlet cannot detect powder leakage through filter bag.	Yes	Basic requirement	EHS	Environ may get contaminated with the product	High	Broken bag detector/solid flow monitor will be considered in the design.	Acceptable	IQ/OQ
7.	Broken bag detector	Broken bag detector is not functioning	Yes	Basic requirement	EHS	Product exposure.	High	If broken bag detector is not functioning due to power off, it will be indicated by alarm.	Acceptable	OQ
8.	Fingers of Filter bag	Finger of filter bag is choked.	Yes	Incomplete drying affects final quality of product.	No	NA	High	Automatic filter shake control shall be provided.	Acceptable	IQ/OQ
9.	Filter bag seal	Filter bag is not sealed properly	Yes	Loss of material. Drying will not be effective.	No	NA	High	• Filter seal shall be with filter locking system. • Filter seal deflation will be indicated by alarm.	Acceptable	IQ/OQ
10.	Sampling port	In process sample vent is not available	Yes	Required to assess the completion of drying process	No	NA	High	• Sampling port to be considering in the design for easy sampling	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
10.				Required to assess the completion of drying process	No	NA	High	Sampling port to be considered in the design for easy sampling.	Acceptable	IQ / OQ
11.	Sampling port	Product exposure to the personnel	No	Does not have any impact on product quality	EHS	Health hazard to the person in contact of product	Low	During sampling, personnel shall wear PPE to avoid the contact.	Acceptable	SOP
12.	Machine Operation	Operator cannot operate the machine	Yes	Process parameters cannot be achieved	Productivity	Machine cannot be operated.	High	Training shall be provided to the operator for the operation of the FBD.	Acceptable	OQ/ SOP
13.	FBD Pressure	Pressure of FBD cannot be monitored	Yes	Basic GMP requirement	No	NA	High	Differential Pressure gauge shall be provided to monitor the relative pressure of FBD.	Acceptable	IQ
14.	Inlet/ Outlet Air Temperature	Temperature of inlet/ exhaust air cannot be monitored & controlled	Yes	Basic GMP requirement	No	NA	High	Temperature sensor cum controller shall be provided for monitoring and controlling of inlet/ outlet air temperature of FBD.	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
15.	Sight glass	Content inside the equipment cannot be observed in running process	Yes	Process cannot be assessed visually	No	NA	High	Sight glass with lamp shall be provided.	Acceptable	IQ
Discharge										
16.	Discharge arrangement	Discharge from product bowl is not easy and complete.	Yes	Product may spill resulting area contamination	EHS/ Operational	Personnel get exposed to the product. Product loss	High	Design should ensure easy and complete manual discharge. Discharge of bowl shall be facilitated by Tippler arrangement.	Acceptable	IQ/ OQ
Cleaning & Material of Construction										
17.	Cleaning	Improper cleaning	Yes	Accumulation of particles leading to cross contamination	No	NA	High	▪ WIP shall be provisioned manually. ▪ All gaskets provided to avoid leakage should be amenable for easy removal & re-fixing for cleaning.	Acceptable	IQ/ SOP

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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
18.	Cleaning	Difficulty in cleaning	Yes	Parts need to be dissembled for proper cleaning	No	NA	Medium	▪ The design shall ensure adequate clean ability (smooth, crevice free surface, MOC SS316 or better surface). ▪ Parts that cannot be cleaned in mounted position e.g. hopper, feeder etc. to be made suitable to dissemble and clean.	Acceptable	IQ
19.	Filter Bag	Filter bag is not cleanable	Yes	Cross contamination	No	NA	High	Dedicated filter bag for the product.	Acceptable	IQ
20.	Material of Construction	▪ Surface and construction of the machine is not compatible to product. ▪ Material reacts with cleaning media like PW, IPA etc.	Yes	It will lead to product contamination due to corrosion	No	NA	High	▪ All product contact metallic surfaces should be of SS 316 or better. ▪ All welds and joints shall be ground finish; metallic surface will have no crevices. ▪ Non Contact surfaces should be SS304 with external surface matt finish.	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
21.	Welding	Welding quality not sufficient	Yes	GMP requirement; Cleaning problems, surface conditions out of specification in case of bad welding quality.	No	NA	High	Standard welding technique: Orbital welding Welding verification reports shall be available	Acceptable	IQ
22.	Gaskets, seals and O rings MOC	Gasket MOC not compatible with product	Yes	▪ Product contamination possible	No	NA	High	▪ MOC should be of food grade (Silicon/PTFE).	Acceptable	IQ
23.	Surface Finishing	Surface Finishing of Internal & external surface insufficient	Yes	▪ GMP requirement; cleaning problems. ▪ Micro-organisms may accumulate on metallic surfaces	No	NA	High	▪ Surface roughness, Ra ≤ 0.5 µm, proven by certificates for internal surface. ▪ Crevice free smooth, rounded corners & smooth surface.	Acceptable	IQ
Safety										
24.	Insulation and cladding of hot air ducts	Exposure of hot surface and dust accumulation	Yes	Insulation without cladding will lead to contamination	EHS	Absence of insulation to the hot surface will lead to accident and loss of utility	Medium	Appropriate insulation followed by SS cladding will be considered in the design	Acceptable	IQ
25.	Air Handling System	Leakage in air path	Yes	Uncontrolled entry of contaminants in the path	EHS	Product exposure to environment	High	Air duct should be tested for leakage during installation.	Acceptable	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
26.	Air Handling System	System cannot maintain the negative pressure within FBD	No	Negative pressure is solely EHS requirement	EHS	Product exposure to environment	Low	Air inlet through suction in exhaust line should create negative pressure within FBD.	Acceptable	OQ
27.	Noise level	More noise is produced by the equipment during the operation	No	NA	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
28.	Rotating & Electrical parts	Rotating & electrical parts are not covered	No	NA	EHS	Accident can take place	High	All rotating & electrical parts should be covered.	Acceptable	IQ
Measuring Instruments:										
29.	Measuring Instruments	Measuring instruments are not within operating range	Yes	Design inadequacy	No	NA	High	Measuring instruments operating ranges should be suitable.	Acceptable	IQ
30.	Measuring Instruments	Measuring instruments could not be calibrated	Yes	Instrument not suitable for use as it may produce false results.	No	NA	High	Instruments should be calibrated and suitable for recalibration	Acceptable	IQ
Control System										

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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
31.	Control System	Control system is not suitable to select process/operational parameter for process control or wrong selection of recipe	Yes	Process optimization and validation is not possible.	No	NA	High	Control panel will be considered in the design.	Acceptable	IQ & OQ
32.	Control System	Critical process parameters could not be monitored.	Yes	Process optimization and validation is not possible.	No	NA	Medium	Control panel will monitor and display the critical process parameters like flow rate, inlet air temperature, bed temperature, exhaust temperature, drying time etc.	Acceptable	OQ
Documentation:										
33.	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
34.	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

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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
35.	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
36.	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
37.	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 unavailability of procedure.	High	SOPs for Operation, Cleaning and maintenance shall be prepared in line with operational and maintenance manual and finalized.	Acceptable	OQ

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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. Fluid Bed Dryer.
- The critical risks pertaining to GMP and other than GMP were analyzed with justification and mitigation procedures.
- For each recognized GMP-risk and other than GMP risks necessary measures are defined. Organizational measures, like SOPs, are also possible measures for special GMP-risks. The availability of these SOPs will be checked during the performance of the OQ.
- The risks where conceptual procedures shall be employed, standard operating procedures (SOPs), Preventive maintenance schedules, Certificates and related documents indicated as mitigation procedures shall be ensured at respective test points.

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

10.0 Abbreviations:

Acronym	Definition
cGMP	Current Good Manufacturing Practice
db	Decibel
EU-GMP	European –Good Manufacturing Practice
GA	General Arrangement
GAMP	Good Automated Manufacturing Practices
GMP	Good Manufacturing Practices
HMI	Human Machine Interface
IQ	Installation Qualification
LCD	Liquid Crystal Display
MOC	Material Of Construction
OQ	Operational Qualification
O & M	Operation and Maintenance Manual
PLC	Programmable Logic Controller
PQ	Performance Qualification
RPM	Revolution per minute
Rh	Relative Humidity
SOP	Standard Operating Procedures
SS	Stainless steel
URS	User Requirement Specification
w.r.t.	With Respect To