FAILURE MODE EFFECT ANALYSIS FOR BE-COATER

Revision	Date	Reason for revision
00		First Issue

FAILURE MODE EFFECT ANALYSIS FOR BE-COATER

Table of Contents

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

FAILURE MODE EFFECT ANALYSIS FOR BE-COATER

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

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

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

FAILURE MODE EFFECT ANALYSIS FOR BE-COATER

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	

FAILURE MODE EFFECT ANALYSIS FOR BE-COATER

5.0 System Description:

Be-Coater machine shall be used for the coating of tablets. The pan size shall be 36 inches. Tablets shall be charged into the pan of the coating machine through charging chute using suitable containment system. The exhaust from the pan is to be interlocked to the containment system such that the tablets cannot be loaded to the pan until the exhaust is running

The e-coater machine shall be facilitated to use for both film coating and sugar coating with changeover. Drum baffles shall be provided to ensure efficient mixing of the product without damage. There is to be full homogeneity of the tablets within 5 revolutions. Supply of hot air and exhaust air shall be arranged to facilitate the coating system through stainless steel plenums positioned on both sides of the perforated coating pan.

PLC based control panel provided with printer shall be mounted on the cabinet for automatic control of all the coating parameters and data logging. An adequate washing system WIP shall be provided for pan with sink having necessary drain connection for removal of waste water. The complete system shall be provided with necessary accessories, including air-handling system with air filtration having HEPA filters in supply and in exhaust.

In this GMP risk assessment all critical components of the Be-coater machine, 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

A typical Risk management process consists of following steps:

r

- 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.

FAILURE MODE EFFECT ANALYSIS FOR BE-COATER

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.

3 (Likely)	Medium	High	High

FAILURE MODE EFFECT ANALYSIS FOR BE-COATER

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.

FAILURE MODE EFFECT ANALYSIS FOR BE-COATER

8.0 Risk Assessment:

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

Column 1: **Serial number** of Risk Assessment item

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

Column 3: **Risks**: Identify the type of risk associated with the process or component. Column 4: Verify that whether there is **GMP risk.**

Column 5: **Justification**: Provide justification for declaring both yes/no for GMP Impact in column 3.

Column 6: For the risk **other than of GMP risk,** write what is the other type of risks e.g. EHS, Operational.

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

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

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

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

Column 9b: **Residual risk level**: After the risk mitigation what is the residual risk level, whether it is acceptable, low or Medium

Column 9c: **Verification**: Write the test point where the risk mitigation strategy will be verified.

FAILURE MODE EFFECT ANALYSIS FOR BE-COATER

S.No	Process steps/component	Risk	G P Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
Charging										
1.	Loading of tablets	Exhaust remains off during charging of tablets	No	Does not have impact on quality of the product	EHS	Required negative pressure is not created during charging. Operator health may be at risk.	High	▪ Charging of Tablets should be through suitable containment system. ▪ The Exhaust system should be interlocked with the charging system so as to create negative pressure.	Acceptable	IQ/ OQ
2.	Inlet air	Uncontrolled temperature	Yes	Inlet air temperature control is process requirement	No	NA	High	Temperature shall be controlled and monitor through PLC.	Acceptable	IQ /OQ
3.	Loading of Tablets	Spillage during transferring of the tablets	Yes	Product Loss, area contamination	No	NA	High	Training of the operators for manual loading so as to avoid spillage during transferring	Acceptable	OQ
Process:										

FAILURE MODE EFFECT ANALYSIS FOR BE-COATER

S.No	Process steps/component	Risk	G P Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
4.	s Inlet Air	▪ Inlet Air is not filtered. ▪ Pressure not maintained.	M Yes	It will lead to product contamination	No	NA	High	▪ Air Filter assembly with HEPA filter and differential pressure indicator will be considered at the air inlet in the design. Provision for PAO port shall be provided. ▪ Pressure switch shall be provided on main air line.	Acceptable	IQ/OQ
5.	Coating Pan	Coating pan without perforations	Yes	It may affect the appearance of the product and drying efficiency	No	NA	High	Perforated coating pan will be considered.	Acceptable	IQ
6.	Coating solution vessel	Sedimentation takes place in Coating solution	Yes	Inconsistent solution will result in uneven coating	No	NA	High	Agitator to be used with the coating vessel.	Acceptable	IQ / OQ
7.	View port with lamp	Content inside the coating pan is not visible during closed condition	Yes	Process monitoring is not possible	No	NA	High	View port with flameproof lamp will be considered in the design.	Acceptable	IQ

N

FAILURE MODE EFFECT ANALYSIS FOR BE-COATER

S.No	Process steps/component	Risk	G P Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
8.	Atomization **s** Pressure	Spraying is not atomized	Yes **M**	Proper coating will not be achieved	No	NA	High	▪ Controlled atomization pressure will be applied to produce the desired spray pattern. ▪ Pressure switch shall be provided to control atomizing pressure. **M**	Acceptable	IQ/OQ/PQ
9.	Coating Pan	Pan RPM cannot be controlled	Yes	Process requirement	No	NA	High	▪ RPM indicator cum controller will be considered in the design. ▪ VFD to be provided to control speed of Pan	Acceptable	IQ / OQ
10.	Spray gun	Solution is dripping from spray gun even after the machine stops	Yes	It may hampers the product quality and appearance	No	NA	High	Suitable design will be considered so that solution will not be dripped from spray guns at time of machine stop.	Acceptable	OQ
11.	Pressure differential pressure	Differential pressure cannot be controlled across the coating pan & isolator	Yes	It will lead to defective coating	No	NA	High	Closed type coating pan shall be considered in the design.	Acceptable	IQ / OQ

N

FAILURE MODE EFFECT ANALYSIS FOR BE-COATER

S.No	Process steps/component	Risk	G P Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
12.	Operations	Tablets do not roll and stick inside the pan	Yes	Non-rolling tablets will not get coated resulting in process failure	No	NA	High	Design of the coating pan with baffles will be considered to move all the tablets and no such spaces would be there where tablets will get stuck	Acceptable	IQ/OQ
13.	HEPA Filter	HEPA filter got clogged	Yes	Air flow will get reduced resulting defective coating	No	NA	High	Differential pressure gauge should be provided for monitoring differential pressure across HEPA filter.	Acceptable	IQ
14.	Exhaust air	Contamination of the environment with the exhaust air	No	Does not have any impact on quality of the product	EHS	Product exposure	Medium	HEPA filter with wet scrubber shall be provided.	Acceptable	IQ
15.	Spray Rate	Desired spray rate cannot be achieved	Yes	Consistent coating could not be achieved	No	NA	High	Spray rate will be regulated by multi head peristaltic pump	Acceptable	IQ / OQ
16.	Spray Gun	Spray gun cannot be fixed at desired position	Yes	Consistent coating could not be achieved	No	NA	High	Spray gun angle/ distance adjustment to be provided in the design of the spray gun assembly.	Acceptable	OQ
17.	Process time	Desired time duration cannot be set and monitored	Yes	It will lead to uncontrolled coating	No	NA	Medium	Provision to be provided to set and monitor process timing	Acceptable	IQ/OQ

FAILURE MODE EFFECT ANALYSIS FOR BE-COATER

S.No	Process steps/component	Risk	G P Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
18.	s Process temperature	Temperature inside the coating pan, bed temperature and exhaust temperature cannot be monitored	M Yes	Process requirement	No	NA	High	Temperature of the critical points (Tablet bed and exhaust) will be monitored and interlinked with inlet air temperature so as to attain desired temperature during entire coating cycle and to assess aftermath	Acceptable	IQ / OQ
19.	Bed sensor	Tablet bed temperature sensor cannot be adjusted.	Yes	Bed temperature cannot be assessed correctly.	No	NA	High	Bed temperature sensor position will be designed so that it can be adjustable according to the bed height	Acceptable	OQ
Discharge										
20.	Discharge Chute	Discharge of tablet cannot be controlled	No	No impact on product quality	EHS	It may lead to product loss	High	Discharge chute be designed to control the transfer of coated tablets without affecting the tablet quality.	Acceptable	IQ/OQ
21.	Discharge Chute	Discharge is not possible in closed condition	No	No impact on product quality	EHS	Product exposure	Low	Discharge shall be inside isolator through RTP.	Acceptable	IQ
Cleaning and Material of Construction										

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

FAILURE MODE EFFECT ANALYSIS FOR BE-COATER

S.No	Process Steps/component	Risk	G P Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
22.	**s** Cleaning	Improper cleaning	**M** Yes	Accumulation of particles leading to Inefficient cleaning process	No	NA	High	▪ Proper cleaning (CIP/ process) method has to be provisioned. ▪ All gaskets provided to avoid leakage **M** should be amenable for easy removal & re-fixing for cleaning. ▪ All bolts, nuts on the exterior part of the equipment shall be provided with cap head or cap nut.	Acceptable	IQ/ OQ
23.	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 / OQ

FAILURE MODE EFFECT ANALYSIS FOR BE-COATER

S.No	Process steps/component	Risk	G P Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
24.	Cleaning s M	Removal of contaminants not possible; Improper cleaning	Yes	Accumulations of coating solution on the internal surface leading to inefficient cleaning	No	NA	High	▪ The CIP system shall be provided with a vessel to generate Hot purified water for washing. ▪ A detergent system should be available for dispensing the cleaning agent during cleaning process.	Acceptable	IQ/ OQ
25.	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 P&ID) ▪ All labelling in English language and according to project standard.	Acceptable	IQ

N

FAILURE MODE EFFECT ANALYSIS FOR BE-COATER

S.No	Process steps/component	Risk	G P Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
26.	s Material of Construction	▪ Surface and construction of the machine is not compatible to product. ▪ Material reacts with cleaning media like PW, IPA etc.	M 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; M metallic surface will have no crevices. ▪ Non Contact surfaces should be SS304 with external surface matt finish.	Acceptable	IQ
27.	Welding	Welding quality not sufficient (Piping)	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
28.	Gaskets, seals and O rings MOC	Gasket MOC not compatible	Yes	▪ Product contamination possible	No	NA	High	▪ MOC should be of food grade (Silicon/PTFE).	Acceptable	IQ

N

FAILURE MODE EFFECT ANALYSIS FOR BE-COATER

S.No	Process Steps/component	Risk	G P Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
29.	Surface Finishings	Surface Finishing of Internal & external surface insufficient	YesM	▪ 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. ▪ Device free smooth, rounded corners & smooth surface.	Acceptable	IQ
30.	Drain	Water is not completely drained	Yes	Water stagnation leads to microbial contamination.	No	NA	High	Water drainage to be considered through bottom discharge to ensure complete drainage	Acceptable	IQ/OQ
Maintenance										
31.	Maintenance	Malfunctions due to worn parts	Yes	Basic GMP requirement	No	NA	High	▪ 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
Safety										

N

FAILURE MODE EFFECT ANALYSIS FOR BE-COATER

S.No	Process steps/component	Risk	G P Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
32.	Moving & electrical parts	Moving & electrical parts are not covered.	No	Does not have any impact on quality of the product	EHS	Operator safety	Medium	All moving & electrical parts are to be covered properly	Low	IQ
33.	Gaskets	Gaskets are not compatible with material handled in equipment	Yes	Product contamination	No	NA	High	Gaskets to be made of approved food grade elastomer	Acceptable	IQ
34.	Gaskets	Joint gaskets are not replaceable	Yes	Worn gasket will contaminate product and affect the integrity	EHS	Result in material leakage	High	All the gaskets should be of replaceable type so as to remove the worn out or damaged gaskets.	Acceptable	IQ
35.	Notification of alarms	Failure of utility supply is not indicated	Yes	Process parameters may get disturbed	EHS	High pressure may cause accident	High	Various utilities like compressed air supply, vacuum supply should be interlocked and indicated by alarm	High	IQ / OQ
36.	Emergency top	Instantaneous stopping of the machine not possible	No	Does not have any impact on quality of the product	EHS	Emergency stop function is required for equipment, personnel and product protection	High	Emergency stop with alarm to be installed on accessible areas	Acceptable	IQ / OQ

FAILURE MODE EFFECT ANALYSIS FOR BE-COATER

S.No	Process steps/component	Risk	G P Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
37.	s Noise level	More noise is produced by the equipment during the operation	M No	Does not have any impact on quality of the product	EHS	High noise may cause deafness and anxiety	Medium	▪ Equipment should be provided with anti-vibration mountings to reduce vibration and noise. M ▪ Noise level shall be below 80 db at a distance of 1 m from the equipment.	Acceptable	IQ/ OQ
38.	Air Handling System	Leakage in air path	Yes	Uncontrolled entry of contaminants in the path	EHS	Product exposure to environment leading to operator health risk.	High	Supply considered with filters. Air duct should be tested for leakage during installation.	Acceptable	IQ &OQ
39.	Air Handling System	System cannot maintain the negative pressure within the pan.	No	Does not have any impact on quality of the product	EHS	In case of overpressure chances of leakage into room	High	System to be designed to meet the negative pressure within the pan and display of differential pressure with respect to room and alarm in case of out of limit.	Acceptable	OQ

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

FAILURE MODE EFFECT ANALYSIS FOR BE-COATER

S.No	Process Steps/component	Risk	G P Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
40.	Containment	The material charging to coating pan is not contained.	No	Does not have any impact on quality of the product	Yes	The product can effect operators health	High	▪ The material charging to coating pan shall be carried out through suitable containment system. ▪ A negative pressure should be provided in the containment chamber.	Acceptable	IQ/ OQ
41.	Containment while sampling	The material may contaminate the personnel working environment.	No	Does not have any impact on quality of the product	Yes	The product can effect operators health	High	▪ Glove ports should be provided in the entire system for easy access to all parts. ▪ A negative pressure should be provided in the containment chamber.	Acceptable	IQ/OQ
42.	Containment	Leakage	No	Does not have any impact on quality of the product	Yes	The product can effect operators health	High	▪ The containment should be leak proof. ▪ Leak test should be conducted.	Acceptable	OQ
43.	Pumps/ Blower	Pump/Blower gets overloaded	No	Does not have any impact on quality of the product	Operational	Product losss	Low	Pump overload protection should be provided	Acceptable	OQ
Measuring Instruments										

FAILURE MODE EFFECT ANALYSIS FOR BE-COATER

S.No	Process Steps/component	Risk	G P Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
44.	Measuring Instruments s	Measuring instruments are not within operating range	Yes M	Design inadequacy	No	NA	High	Measuring ranges shall be defined	Acceptable	IQ
45.	Measuring Instruments	Measuring instruments could not be calibrated	Yes	Instrument not suitable for use as it may produce false results	No	NA	High	M Instruments should be calibrated and suitable for recalibration	Acceptable	IQ
Control and Monitoring System										
46.	Man-machine Interface	Process / process status not visible for operating personnel	Yes	Operating personnel must have knowledge on the process status	No	NA	High	Machine shall be fitted with adequate display and clean room suitable key board for operation.	Acceptable	IQ
47.	Man-machine Interface	Display language not identified.	Yes	Pre-requisite for the GMP compliant operation	No	NA	High	▪ The language on the display of MMI should be English language only.	Acceptable	OQ
48.	PLC/ Control System	Monitoring/recording and documentation of GMP relevant data not possible	Yes	Basic GMP requirement	No	NA	High	▪ It should be possible to monitor/record GMP relevant data (e.g. recorder with compliance to GAMP 4 / 21 CFR, Part 11 etc.). ▪ Batch records to be defined.	Acceptable	OQ

FAILURE MODE EFFECT ANALYSIS FOR BE-COATER

S.No	Process steps/component	Risk	G P Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
49.	PLC/ Control System	Controlling of critical process parameters not possible	Yes	Basic GMP requirement	No	NA	High	▪ PLC should be able to control critical process parameters like Inlet/ Exhaust air, Pan speed, Inlet air temp., Spray rate, Spray On/ Off time, Dosing count, Atomizing pressure etc.	Acceptable	OQ
50.	PLC/ Control System	Control system does not detect failures and generate alarms	Yes	Process optimization and validation is not possible	No	NA	High	Failure of set parameters gets indicated as alarms and machine stops.	Acceptable	OQ
51.	PLC / Control system	Power failure / emergency stop	Yes	Process out of specification	No	NA	High	▪ Operator settings unchanged and restored after emergency stop / power failure; ▪ Alarm message; ▪ Machine must not start automatically without operator intervention after incident ▪ SOP for 'Maintenance and operation of Tablet compression machine'.	Acceptable	OQ

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

FAILURE MODE EFFECT ANALYSIS FOR BE-COATER

S.No	Process steps/component	Risk	G P Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
52.	s PLC / Control system	Status parameters not clear	M Yes	Process for the particular product at particular stage can't be regulated easily.	No	NA	High	▪ Status parameters should remain displayed at each process stage. ▪ The flow of the process shall be provided with the help of arrows. ▪ Alarm should also be visualized along with the fault displayed.	Acceptable	OQ
53.	Accessibility to PLC	Parameter settings not identified universally	Yes	Basic GMP requirement	No	NA	High	▪ Parameters settings should be in numeric only.	Acceptable	OQ
54.	y PLC / Control system	No protection of PLC against manipulation & changes.	Yes	Basic GMP requirement.	No	NA	High	▪ 3 level password protections should be provided. ➢ Level 1: for operator settable parameters. ➢ Level 2: for editing cycle parameters. ➢ Level 3: for admin/ engineering level setting.	Acceptable	OQ
Documentation										

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

FAILURE MODE EFFECT ANALYSIS FOR BE-COATER

S.No	Process steps/component	Risk	G P Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
55.	**s** User	Faulty operation & maintenance	**M** 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, setting parameters, trouble shooting & maintenance related activities.	Acceptable	OQ/ SOP
56.	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
57.	User	Unauthorized person tries to start/stop the system	Yes	Untrained persons may damage the system or product quality may be affected	No	NA	High	▪ System should not start without password. ▪ Key-switch should be provided for system power up.	Acceptable	IQ/ OQ

FAILURE MODE EFFECT ANALYSIS FOR BE-COATER

S.No.	Process Steps/component	Risk	G P Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
58.	**s** Vendor	Technical documentation from vendor not adequate	**M** Yes	Adequate technical documentation is basic GMP requirement	No	NA	High	▪ Vendor documentation (English) shall comprise: -DQ, IQ and OQ -Data sheets **M** -Material certificates -Operating instructions -Maintenance instructions and intervals -Calibration certificates -Software backup -Parts lists(sufficient detailed: part number, supplier, type) ▪ Drawings - P&I-diagrams - Electrical diagrams -As built GA drawing ▪ Filter certificates ▪ Running trial certificate. ▪ Certificate of bought out components.	Acceptable	IQ

N

FAILURE MODE EFFECT ANALYSIS FOR BE-COATER

9.0 Summary and Conclusion:

E e

- 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. Be-Coater Machine.
- The critical risks pertaining to GMP and other than GMP were analyzed with justification and mitigation procedures.
- For each recognized GMP-risk and other than GMP risks necessary measures are defined. Organizational measures, like SOPs, are also possible measures for special GMP-risks. The availability of these SOPs will be checked at the time of accomplishment of OQ of the machine.
- To control the risk, various mitigation methods shall be verified through SOPs ,operation & maintenance manuals, and calibration certificates at respective verification points
- Based on Risk Assessment, the URS shall be prepared.

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

FAILURE MODE EFFECT ANALYSIS FOR BE-COATER

10.0 Abbreviation:

Acronym	Definition
cGMP	Current Good Manufacturing Practice
db	Decibel
EU-GMP	European –Good Manufacturing Practice
GA	General Arrangement
MMI	Man Machine Interface
IQ	Installation Qualification
OQ	Operational Qualification
DQ	Design Qualification
MOC	Material Of Construction
EHS	Environment Health Safety
IBC	In process Bulk Container
O & M	Operation and Maintenance Manual
PLC	Programmable Logic Controller
RPM	Revolution per minute
SOP	Standard Operating Procedures
SS	Stainless steel
URS	User Requirement Specification
VFD	Varibale Frequency Drive
HEPA	High Efficiency Particulate Air Filter
PPE	Personnel Protective Equipment
PW	Purified Water
IPA	Iso Propyl Alcohol
PTFE	Poly tetra fluoro Ehtylene