Risk Assessment Document

Solution Preparation Tank

RISK ASSESSMENT FOR SOLUTION PREPARATION TANK

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RISK ASSESSMENT FOR SOLUTION PREPARATION TANK

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		
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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

Compounding vessel shall be used to mix the ingredients with the help of Agitator. Vessel shall be jacketed and insulated to control temperature and prevent any heat loss. The temperature during the process shall be controlled via circulation of utilities in the jacket with a centrifugal pump. Heat exchanger is needed to maintain the process at a constant temperature. The compounding vessel should have top spherical top head to accommodate all the required nozzles.

The equipment should consist of following parts in order to run operation smoothly.

S.No.	Description	Purpose
1.	Vessel	To mix the content
2.	Agitator	Bottom driven Magnetic mixer with variable frequency drive and baffle
3.	Jacket	To be used for cooling or heating the material in the vessel
4.	Nozzle connections	To be used for CIP/SIP/transfer/Sampling

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:**

  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.

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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.

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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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8.0 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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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)
A.	**Design:**									
1.	Capacity	Insufficient capacity	Yes	Batch requirement cannot met	No	NA	Yes	Equipment shall be of suitable capacity	Acceptable	DQ/IQ
2.	Location	Wrong positioning of the equipment	Yes	It can affect the process flow	No	NA	Yes	Drawings shall be considered strictly to avoid the possibilities of any deviation from existing location	Acceptable	DQ/IQ
3.	Working Space	Insufficient space	Yes	Equipment cannot be Maintained properly	No	NA	Yes	Equipment must be approachable for suitable cleaning and maintenance	Acceptable	DQ/IQ
4.	Clean-ability	Contamination of Clean-rooms	Yes	Surface of the equipment may encourage dust accumulation/ microbial growth	No	NA	Yes	The design must ensure easy clean-ability by providing smooth surface finishes and round edges.	Acceptable	IQ/OQ
B.	**Charging**:									
5.	Charging of raw material	Spillage during charging of raw material	Yes	• Loss of raw materials • chances of cross contamination	EHS	Health hazard to the person in contact of product	Yes	Charging port should be designed wide enough for appropriate feeding method of input processed materials& excipients.	Acceptable	IQ/OQ
C.	**Process**:									

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6.	Agitator	Agitator not working properly	Yes	Mixing may not be effective	No	NA	Yes	• The agitator shall perform well at set operating range of RPM for proper mixing • The RPM beyond the set limit shall notify the operator with alarm and shut down the process • To control the speed, agitator shall be provided with Variable frequency drive with indicator	Acceptable	DQ. IQ/OQ
7.	Sight glass & Light glass	There is no Sight glass & Light glass	Yes	Inspection during operation cannot be done	No	NA	Yes	Sight glass & Light glass be considered in the design	Acceptable	DQ/IQ

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8.	Jacketed vessel	Product temperature cannot be maintained during the process	Yes	Insufficient/Excess temperature may lead to product deterioration	No	NA	Yes	• Pneumatically controlled inlet/outlet connection for Chilled water/hot water supply & drain port should be provided within the vessel jacket • Jacketed vessel shall be considered	Acceptable	IQ/OQ
9.		Heat exchanger Coils may leak	Yes	contaminated product	No	NA	Yes	• Temperature sensor shall be provided to monitor and control the temperature • Alarm shall be considered in the design to notify the operator any variation from set value	Acceptable	IQ, OQ

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10.	Process Temperature	Uncontrolled temperature	Yes	Product deterioration	No	NA	Yes	• Temperature sensor, indicator and controller shall be provided to monitor, indicate and control the jacket temperature • The temperature beyond the set limit shall notify the operator with alarm and shut down the process	Acceptable	IQ/OQ

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11.	Pressure	Pressure cannot be monitored	Yes	Pressure monitoring is required since excess/low pressure may deteriorate the product	No	NA	Yes	• Pressure indicator shall be provided • The pressure beyond the set limit shall notify the operator with alarm and shut down the process • Safety valve shall be provided on vessel to relieve excess pressure	Acceptable	IQ/OQ
12.		Vessel cannot withstand the desired operating pressure	Yes	Product deterioration	Operational	Process hold up may occur	Yes	Hydro test verification shall be performed on Vessel	Acceptable	OQ
13.	Process time	Desired time cannot be set and monitored	Yes	Chances of error due to manual control on time	No	NA	Yes	Timer shall be provided to monitor, control and record process time.	Acceptable	IQ/OQ

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14.	pH	Product pH cannot be measured	Yes	Process requirement	No	NA	Yes	• pH probe shall be provided • The pH of product within the vessel beyond the set limit shall notify the operator with alarm	Acceptable	IQ/OQ
15.		pH cannot be adjusted	Yes	Product deterioration	No	NA	Yes	• An inlet port for acid/alkali addition shall be provided	Acceptable	IQ
16.	Cleaning In Place	During cleaning in place activity water spray is not reachable to all parts of Vessel like nozzles of material charging	Yes	Cross contamination may occur	No	NA	Yes	• Spray ball should cover entire area with 360^0 spray • Spray ball should clean all the internal surfaces at specified flow rate & pressure of cleaning agent	Acceptable	IQ/OQ

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17.	Sampling	Sampling is not possible	Yes	Sampling is required during validation study and routine analysis.	No	NA	Yes	Sampling valve shall be provided	Acceptable	IQ
18.	PID valve	Uncontrolled pneumatic operations	Yes	Product deterioration	No	NA	Yes	PID valve shall be provided	Acceptable	IQ
19.	Vent Filter	Lack of filter in the vent	Yes	It can result in contamination of the product	No	NA	Yes	Vent filter shall be considered in the design	Acceptable	IQ
20.	Alarms	No indication when critical parameters are out of limit	Yes	Product wastage	• EHS • Operational	• Accident may occur • Process hold up may occur	Yes	Equipment shall generate audio-visual alarm	Acceptable	OQ
21.	Drives and Motor	Uncontrolled speed	No	Process optimization	No	NA	Yes	Variable frequency drive shall be considered in the design	Acceptable	IQ
22.	Spare parts	Maintenance of machine	No	NA	Operational	Scheduled/ unscheduled maintenance of machine	No	Spare parts/ list of spare parts shall be provided by the vendors	Acceptable	DQ/IQ
D. Discharge:										
23.		Product cannot be discharged	Yes	Process requirement	No	NA	Yes	Discharge valve at the bottom of the vessel should be provided	Acceptable	IQ

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24.		Incomplete discharge of the Product	Yes	Yield loss	No	NA	Yes	• No dead end should be there near the discharge valve • Vessel Should be checked for complete drainability verification Test	Acceptable	IQ/OQ
E. Equipment Automation:										
25.	Process control	Control of process parameters could not be monitored	Yes	Control of critical process parameter	No	NA	Yes	PLC control system shall be considered in design for monitoring the critical process parameters.	Acceptable	IQ/OQ

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								Mitigation Method (9a)	Residual Risk Level (9b)	Verification (9c)
F.	**Process**									
26.	Documentation	All events are not recorded	No	Documentation requirement	No	NA	Yes	Control system interfaced with printer, shall print process parameters.	Acceptable	IQ/OQ
27.	Control System	Control system is not suitable to select process / operational parameter for process control	Yes	To select product specific process parameters	No	NA	Yes	Suitable Control system with HMI for selection of process parameter should be considered	Acceptable	IQ/OQ
28.	Control System	Malfunction	Yes	Correct functioning of the system is a basic requirement for GMP-compliant operation	No	NA	Yes	• Verification of control system during qualification • Overload for all pumps, drives and belts	Acceptable	OQ
29.	Control System	Control system couldn't detect the failures	Yes	Product may be exposed to room air unknowingly and may lead to cross-contamination.	EHS	Health hazard to the person in contact of product	Yes	Control system shall intimate the respective failures with alarm.	Acceptable	IQ/OQ
G.	**Cleaning and Material of construction:**									

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30.	MOC	Product contact surface material is not cleanable	Yes	Unclean-able surfaces lead to product contamination.	No	NA	Yes	• Contact surfaces shall be of SS 316L with internal mirror finish without crevices. • Weld and joints, dozing nozzles should be ground finish	Acceptable	IQ
31.	MOC	Product non-contact parts are not suitable for cleaning	Yes	Product contamination and susceptible for corrosion	No	NA	Yes	Product non-contact metal surfaces should be of SS 304 or better.	Acceptable	IQ
32.	Welding	Welding quality not sufficient	Yes	• Cleaning problems • Surface conditions out of specification • Leaky connection in case of bad welding quality.	No	NA	Yes	• Weld inspection report required • Weld area should be smooth finished	Acceptable	IQ

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33.	Machine Parts	Parts cannot be dissembled	Yes	Proper cleaning will not be feasible	No	NA	Yes	Parts that cannot be cleaned in mounted position to be made suitable to dissemble or having TC joints and clean.	Acceptable	IQ/OQ
H. Safety:										
34.	Gaskets	Joint gaskets are not replaceable	Yes	Cross-contamination	EHS	Containment failure in case of eroded gaskets	Yes	All gaskets shall be replaceable	Acceptable	OQ
35.		Gaskets are not compatible with material handled in equipment	Yes	Contamination	No	NA	Yes	All gaskets, seals, O-rings shall be inert and food grade in nature	Acceptable	IQ
36.	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	Yes	Noise level shall be below 75 db at a distance of 1 m from the equipment.	Acceptable	OQ
37.	Emergency stop	Emergency stop not provided	Yes	Product may damage in case of emergency situation and will lead to increased rejection	EHS	Safety requirement	Yes	Emergency stop function should be provided on accessible areas	Acceptable	IQ/OQ

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38.	Closure of the rotating parts	Appropriate closure of the rotating parts is not provided.	No	NA	EHS	It may lead to accident	Yes	Appropriate closure of all the rotating parts.	Acceptable	IQ
39.	Lubrication system	Lubricant migrates into product through couplings	Yes	It will cause contamination	No	NA	Yes	Lubrication system must be leak proof. Lubricant must be of food grade	Acceptable	IQ
40.	Power	Power Failure	Yes	In-complete process	No	NA	Yes	Provision of UPS for PLC	Acceptable	IQ/OQ
41.		Power recovery is not warned	No	NA	EHS	Staff protection	Yes	Equipment starts with human intervention only. After regain of power the equipment should start from the step it stopped	Acceptable	OQ
42.	warning stickers	The warning stickers are not provided on hot surfaces	No	It can be hazardous to operator	No	Operator safety	Yes	Warning stickers shall be placed on all hot external surfaces. External surfaces not be more than 40^0C.	Acceptable	IQ/OQ
43.	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	Yes	Proper earthing shall be considered in the design	Acceptable	IQ

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44.	Construction	Design of equipment is not flameproof or explosion proof	No	No impact on the product	EHS	Organic solvents handled may lead to fire or explosion	Yes	Equipment shall be considered of flameproof and explosion proof construction	Acceptable	IQ/OQ
I.	**Measuring Instruments:**									
45.	Measuring Instruments	Measuring instruments are not within defined range and accuracy	Yes	Improper monitoring of Process parameters	No	NA	Yes	Ranges shall be defined for various parameters	Acceptable	IQ/OQ
46.		Measuring instruments could not be calibrated	Yes	Instruments are not suitable for calibration.	No	NA	Yes	Must be calibrated and suitable for calibration	Acceptable	IQ/OQ
J.	**Documentation:**									
47.	Documentation	Critical surfaces are not tested for MOC and test reports are not provided	Yes	Lack of documented evidence	No	NA	Yes	• Material test certificate, Welding certificates, lubricant food grade certificates shall be provided. • Guaranty/Warranty certificates shall be provided.	Acceptable	IQ/OQ

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48.	Documentation	Instruments are not provided with calibration certificate	Yes	Lack of documented evidence	No	NA	Yes	Calibration certificate shall be provided	Acceptable	IQ/OQ
49.	Documentation	Equipments is not provided with design and functional specification	Yes	Qualification requirement	No	NA	Yes	• Functional and design specification • Spare part lists, HMI functions with screen shot • List of failure indications • Final as built diagram • P&I-diagrams • Electrical diagrams • Functional design specification • All qualification documents • Drawings shall be provided	Acceptable	IQ/OQ

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50.	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
51.	Standard Operating procedure	Standard operating procedures are not available.	Yes	In lack of standard operating procedures critical operations cannot be carried out successfully resulting process failure.	Operational	Productivity may be reduced due to unavailability of procedure.	Yes	SOPs for Operation, Cleaning and maintenance, Trainings shall be prepared in line with operational and maintenance manual and finalized.	Acceptable	IQ/OQ

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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. Solution Preparation Tank
- 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 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