Risk Assessment Document
For
Sticker Labeling Machine

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RISK ASSESSMENT FOR STICKER LABELING MACHINE

1 Introduction

According to the definition, given in Annex 15 to the EU-GMP-Guide, 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 for the equipment is performed as basic GMP/ EHS-Risk Assessment, which shall help to identify important GMP/ EHS-requirements.

2 Aim of 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.

3 Reference Documents/ Drawings

S.No.	Document Title	Document Number
1.	Validation master plan	

4 Equipment/ System Description

This risk assessment is conducted for a Sticker Labeling Machine, which shall consist of the following main components:

- **Vials/ Ampoules in feed:** Vials/ Ampoules from Inspection machine shall be transferred manually or automatically to Sticker Labelling Machine.
- **Label in feed unit:** To feed the label for labelling to the Vials/ Ampoules.
- **Bar code scanner for the label:** Required For assuring that the appropriate and correct labels are being used as per the product specification by scanning the same.
- **Label coding unit with camera facility:** For coding the labels with the batch details and inspecting the labeling and coding quality with the camera.
- **Labeled Vials/ Ampoules out feed unit:** For discharging the labeled Vials/ Ampoules for blister packing.
- **Conveying unit:** For conveying the vials/ ampoules from vial/ampoule in feed to the vial/ampoule out feed

Most of the possible risk concerning the handling/ operation of the Sticker Labeling Machine has been considered in this RA document.

5 Participants

Name	Designation/ Department	Signature/ Date

6 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.

- 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 the proposed sterile formulation facility.
  The objectives of this risk assessment are to:
  • Review the design around a structured methodology
  • Identify the failure modes and associated risks
  • Check if the proposed control measures are adequate
  • Identify recommendations to obtain a more acceptable risk level if required

6.1 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 Hygiene level of the manufacturing areas 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 hygiene level of the manufacturing and supporting areas
- Risks related to appropriate utilities and their control (eg. power source, compressed air etc.)
- Risks related to calibration/ preventive maintenance
- Risks related to protection of the environment and health & safety of personnel.

- Risks related to cleaning & sterilization
- Risks related to unidirectional flow of the material
- Risks related to cross contamination of the products
- Risks related to entry and exit of personnel and material.
- Risks related to all the environment features of the manufacturing areas.
- Risks related to requirement of particular rooms for different activities.
- Risks related to environment health and safety of personnel.

6.2 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

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.

Level	Descriptor	Example detail description
		• 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.

7 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 the 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** in terms of Yes/ No.

Column 5 : **Justification:** Provide justification for declaring both Yes/ No for GMP impact in column 4.

Column 6 : For the risk **other than of GMP impact**, write that what is/ are the type of risks e.g. EHS, operational, etc.

Column 7 : **Justification:** Provide justification for considering the 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 the following three sections:
Column 9a	:	**Mitigation Method:** Write the risk mitigation strategy as considered in the 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 document:** Write the test point where the risk mitigation strategy will be verified.
Column 10	:	**Status of RA:** Mention the status of the Risk assessment point i.e. whether it is ‘Closed” or “Open”, after the execution/ approval of the Test document.

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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 (9)			Status of RA (10)
								Mitigation Method (9a)	Residual risk level (9b)	Test Document (9c)	
Charging											
1.	Feeding of the Ampoules/Vials	Joint between container & conveyor belt may have space in between	No	NA	Operational	Ampoules/vials may not get properly arranged & thus may experience damage	Low	Cassette system should be followed for feeding of the ampoule/vials into the conveyor belt.	Acceptable	IQ	
2.	Feeding of ampoules/vials	Feed rate cannot be controlled	No	NA	Operational	Uncontrolled feeding of product will lead to frequent breakdown and loss of productivity.	Medium	Feed rate should be controlled with control of vibration intensity. Turn Table/Conveyor shall have sufficient feed manually.	Acceptable	IQ & OQ	
Process											
3.	Change parts	Provision for change parts is not provided.	No	NA	Operational	Labelling of ampoules/vials of different sizes and in variable labeling format is not feasible.	Medium	Machine should be provided with required change parts to label different size ampoules/vials in desired format.	Acceptable	IQ	
4.	Process control	Process parameters such as machine speed, vacuum, pressure etc. cannot be monitored and controlled	Yes	Operation cannot be run in control	No	NA	High	Process parameters will be displayed and control by PLC/HMI	Acceptable	OQ	
5.	In-process control	Over-printing is incorrect or illegible.	Yes	Incorrect or illegible printed matter will mislead the patient lead to market complaint.	No	NA	High	• Inspection of the printed matter and over-printed matter will be done initially and intermittently during entire operation. • SOP-In Process control shall be provisioned.	Acceptable	IQ & OQ	
6.	Lubricant System	Lubricant migrates onto the ampoules/vials.	Yes	It will cause improper labeling or may hamper the printed labels.	No	NA	High	Lubrication system must be leak proof.	Acceptable	OQ	

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7.	Labeling	Labeling may not be on proper position	Yes	Product information will not be completely displayed as intended	No	NA	High	Optic systems shall be available so that the positioning of labels remains the same as intended.	Acceptable	IQ & OQ	
8.	Overprinting	Overprinting is not feasible	Yes	Batch identity cannot be overprinted	No	NA	High	Provision for overprinting should be considered in the design.	Acceptable	IQ & OQ	
9.	Overprinting	Overprinting done may not be feasible & thus leading to wastage	Yes	Product information will remain unidentified	No	NA	High	No Object-no label-no overprinting system should be considered in the design of equipment	Acceptable	IQ & OQ	
10.	Label cutting	Labels are cut with undesired printed matter	Yes	Product may be produced with incomplete information	No	NA	High	Labeled ampoules/vials will be checked intermittently during operation as per In process check SOPs.	Acceptable	OQ & SOP	
11.	Visual inspection system	No provision for online inspection of labelled ampoules/vials.	Yes	• Unlabelled and mislabelled vials & ampoules will mix with good ampoules/vials. • Incorrect or illegible printed matter will mislead the patient lead to market complaint.	No	NA	High	• Vision System with 2 D Matrix code, RSS code, Bar code, Pharma code & OCV/ OCR system for checking coding on labels shall be provided. • Ampoules/Vials having wrong OCR should be rejected with pneumatic rejection system. • Miscoded vials/ampoules read by the camera. The HMI display NO/Bad Barcode. • Production counter will not increment by the number of miscoded vials/ampoules.	Acceptable	IQ & OQ	

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12.	Missing label detection	No provision to detect the missing label on the ampoules/vials.	Yes	Product may be produced with incomplete information.	Operational	Market complaint	High	• Label detection sensor shall be provided to check the presence of label on vials & ampoules. • Unlabelled vials/ampoules sense by the Label detection on product sensor and triggered by the ejection system.	Acceptable	IQ & OQ	
13.	Compressed air	Insufficient pressure	Yes	Equipment operation will be disturbed	No	NA	High	• PRV/ Pressure switch/ transmitter should be provisioned at compressed air inlet to monitor & control compressed air pressure along with alarm provision. • Equipment or process will not start in case of no or less compressed air supply.	Acceptable	IQ & OQ	
14.	Online inspection	No provision for online inspection of labelled ampoules/vials.	Yes	Unlabelled and mislabelled vials & ampoules will mix with good ampoules/vials.	No	NA	High	• Camera system shall be provided for inspection of print coder, correct mater, and proper label position on vials/ampoules. • In case of incorrect or illegible prints machine will stop with alarm.	Acceptable	IQ & OQ	
15.	Process automation	Process parameters are not controlled automatically.	Yes	Possibility of human error leads to a process which is not validated	No	NA	High	• The System shall be PLC based and fully automatic. • The equipment shall control & detect failure mode automatically.	Acceptable	IQ & OQ	
16.	Man-machine Interface	Process / process status not visible for operating personnel.	Yes	Operating personnel must have knowledge on the process status	No	NA	High	MMI shall be provided with adequate display and clean room suitable key board for operation and entering process parameters.	Acceptable	IQ	

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17.	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 shall be English language.	Acceptable	OQ	
18.	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 should get indicated as alarms and necessary interlocks should be in place.	Acceptable	OQ & PQ	
19.	PLC / Control system	Status parameters not clear	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. ▪ Alarm shall also be visualized along with the fault displayed.	Acceptable	OQ	
20.	PLC / Control system	No protection of PLC against manipulation & changes.	Yes	Basic GMP requirement.	No	NA	High	▪ Minimum 3 level password protection shall be provided for the system. ➢ Level 1: Operator ➢ Level 2: Supervisor ➢ Level 3: Admin/ Manager ▪ System shall allow only authorized users to access system and change parameters. ▪ All users shall be provided with unique passwords.	Acceptable	OQ	
21.	Accessibility to PLC	Parameter settings not identified universally	Yes	Basic GMP requirement	No	NA	High	Parameters settings shall be in numeric only.	Acceptable	OQ	
22.	PLC / Control system	Time measurement works incorrect	Yes	Process cannot be carried out using validated parameters.	No	NA	High	▪ PLC Clock verification shall be performed during qualification. ▪ Time synchronization of system clock shall be done with centralized	Acceptable	OQ & SOP	

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								Mitigation Method (9a)	Residual risk level (9b)	Test Document (9c)	
								server clock. ▪ Time verification of the system clock shall be performed at frequent intervals as per SOP.			
23.	Labeled ampoule/vial counting	Labeled ampoule/vial output cannot be assessed	Yes	Yield cannot be monitored	No	NA	Medium	Ampoule/vial counter sensor to be considered in the design	Acceptable	IQ & OQ	
24.	PLC / Control system	Power failure/ emergency stop	Yes	Process out of specification	Safety	Unsafe if start automatically on restoration of power	High	▪ Operator settings shall remain unchanged and restored after emergency stop/ power failure; ▪ Alarm message; ▪ On power failure equipment should come to rest to protect operator, equipment itself & the articles. ▪ Provision of UPS to the control system. ▪ Machine shouldn't start automatically without operator intervention after incident. ▪ SOP for "Operation and Maintenance of Sticker Labeling machine" should mention action to be taken in case of power failure.	Acceptable	IQ, OQ & SOP	
25.	Machine operation	Operator and staff is not trained	Yes	Untrained operators may affect the product labeling accuracy & quality	EHS	Chances of accidents	Medium	Proper training should be delivered to operator and staff by the vendor	Acceptable	OQ	
Discharge:											
26.	Discharge	Variation in ampoule/vial out feed process	Yes	Ampoule/vial may experience harm due to abrasion & attrition	No	NA	High	Low air pressure safety alarm should be provisioned at ampoule/vial ejection area, which will result in continuous & smooth outflow of the	Acceptable	IQ & OQ	

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								ampoules/vials.			
27.	Out feed	Maximum accumulation at out feed.	No	NA	Operational	Ampoules/vials may fall off due to high accumulation at out feed	Medium	▪ Out feed occupancy sensor shall be provided to detect maximum accumulation. ▪ Machine shall stop in case of full capacity at out feed.	Acceptable	IQ & OQ	
28.	Supply reels band	Process remain continue even in the absence of reel	Yes	▪ Product information not delivered to the user as intended. ▪ Information remains unidentified.	No	NA	High	▪ Low reel alarm should be provisioned. ▪ Optic sensor should be provisioned to sense label at the out feed.	Acceptable	IQ & OQ	
29.	Reject ampoule/vials discharge	Rejected ampoule/vial are mixed with good blisters	Yes	Ampoule/vial without labels may go with labeled ampoule/vial lead to market complaint.	No	NA	High	Rejected ampoule/vial chute should be provided. It will be attached to the rejection box.	Acceptable	IQ & OQ	
Cleaning and Material of construction:											
30.	Surface	External surface of equipment is not suitable	Yes	May lead to the clean room contamination	No	NA	Medium	Supporting structures and frames installed inside clean rooms shall be made up of SS 304 or better grade stainless steel.	Acceptable	IQ	
31.	Finishing	External finish of equipment is not proper.	Yes	May lead to the microbial growth	No	NA	Medium	External surface should be free from sharp edges, corners, crevices etc., all metallic external surface shall be matt or mirror finished.	Acceptable	IQ	

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32.	MOC	Ampoule/vial contact surface material is not cleanable	Yes	Uncleanable surfaces lead to ampoule/vial outer surface contamination.	No	NA	High	Ampoule/vial contact metal surfaces shall be of SS 304 or POM.	Acceptable	IQ	
33.	Welding Joints	Weld joints not ground properly		Uneven and improperly ground weld joints will form a space for dust accumulation	No	NA	High	All welds shall be grounded to smooth finish.	Acceptable	IQ	
34.	Dismantling of equipment	Machine cannot be dissembled.		Parts need to be dismantled for proper cleaning.	No	NA	Medium	Parts, which cannot be cleaned in mounted position, to be made suitable to dismantle and clean manually.	Acceptable	IQ	
35.	Labeling of components	Labeling of components/ media inappropriate	Yes	Prerequisite for qualification &maintenance	No	NA	Medium	▪ Unique identity number/ flow direction should be provided on components/ media, operator panel, etc. (e.g. according to P&ID) ▪ Labels affixed on the equipment should be heat resistant. ▪ All labelling shall be done in English language and according to P&ID.	Acceptable	IQ	
Safety											
36.	Electrical system	▪ Electrical systems are not verified for safety. ▪ Earthing not provided for equipment.	No	It will not affect the sterilization process	EHS	May lead to an accident	Medium	▪ All electrical systems shall be tested for safety and shall be provided with safety markings e.g. C.E. marking. ▪ Electrical parts shall be covered. Proper earthing shall be provided for the equipment.	Acceptable	IQ	

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37.	Noise level	More noise is produced by the equipment during the operation		NA	EHS	High noise may cause deafness and anxiety	High	Noise level shall be below 75 db at a distance of 1 m from the equipment.	Acceptable	OQ	
38.	Emergency stop	Instantaneous stopping of the equipment 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 shall be installed on accessible area, along with alarm provision.	Acceptable	IQ & OQ	
39.	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 shall be covered properly.	Acceptable	IQ	
40.	Maintenance	Malfunctions due to worn parts	Yes	Basic GMP requirement	No	NA	High	▪ Machine shall be easy to maintain. ▪ Preventive maintenance procedure shall be provided by the vendor. ▪ The unit should contain necessary protection devices to ensure that the equipment & the article remain in a safe condition. ▪ Preventive maintenance SOP shall be prepared.	Acceptable	IQ & SOP	
Measuring Instrument											
41.	Measuring Instruments	Measuring Instruments not suitable	Yes	Improper measurements	No	NA	High	▪ Measuring Instruments installed should have suitable measuring range. ▪ Operational range of Measuring Instruments shall be greater than equipment's working range. ▪ Measuring Instruments should have appropriate accuracy.	Acceptable	IQ	

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42.	Measuring instruments	Measuring instruments not calibrated	Yes	Non-calibrated measuring instruments may lead to false machine functions	No	NA	High	▪ Measuring instruments shall be calibrated, traceable to national or international standards. ▪ Re-calibration of instruments should be possible.	Acceptable	IQ	
43.	GMP relevant measurement instruments	Instruments cannot be dismounted	Yes	Defective instruments must be dismounted for exchange and calibration	No	NA	High	▪ Mounting of instruments should give the possibility for dismounting and replacement. ▪ Constructional solution: easy access for re-calibration activities shall be provided.	Acceptable	IQ	
Documentation											
44.	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, setting parameters, troubleshooting & maintenance related activities.	Acceptable	OQ	
45.	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 shall be reviewed with all aspects and approved. ▪ Vendor support shall be taken for completion of all stages of the qualification.	Acceptable	OQ	

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46.	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 shouldn't start without password. ▪ Physical entry to equipment room shall be restricted OR ▪ Key switch should be provided for operation of the system	Acceptable	OQ	
47.	Vendor	Technical documentation from vendor not adequate	Yes	Adequate technical documentation is basic GMP requirement	No	NA	High	Following documents shall be provided by vendor (in English): ▪ DQ/ FS, IQ and OQ documents ▪ Material certificates & surface finish reports ▪ O&M manual ▪ Calibration certificates of all instruments ▪ Bought out components manual ▪ Software backup ▪ Parts list (sufficient details - part no., supplier, type etc.) ▪ Drawings (P&ID, GA, Power wiring etc.). ▪ Certificates of bought out components. ▪ Disaster recovery procedure	Acceptable	IQ	

8 Summary & Conclusion

- The Risk Assessment was performed to establish the design parameters of the equipment so as to meet the desired performance of the equipment i.e. Sticker Labeling Machine.
- The critical risks pertained 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".*

9 Abbreviations

EU-GMP	:	European – Good Manufacturing Practice
EHS	:	Environment Health Safety
PLC	:	Programmable Logic Controller
MMI	:	Man Machine Interface
GMP	:	Good Manufacturing Practice
OCR	:	Optical Character Reorganization
POM	:	Polyoxymethylene
RA	:	Risk Assessment
NMT	:	Not More Than
SOP	:	Standard Operating Procedure
USFDA	:	United State Food & Drug Association
SS	:	Stainless Steel
db	:	Decibel
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PQ	:	Performance Qualification
O&M	:	Operation and Maintenance
GA	:	General Arrangement
IPSI	:	Integrated Project Services International, New Delhi

10 Revision History

Date	Revision	Reason for Revision
	00	New Document