PRE RISK ANALYSIS FOR AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELLING MACHINE
(CEPHA BLOCK)

RISK ASSESSMENT REPORT BY FMEA

Product/System/Equipment	**AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELLING MACHINE**
Risk Assessment Report No.	
Report Date	

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DOCUMENT APPROVAL:

This risk analysis study for the preapproval of report by following:

Responsibility	Department	Name	Signature	Date
Prepared by	Quality assurance			
Reviewed by	Production			
	Quality control			
	Engineering			
	Store			
	Quality assurance			
Approved by	Head-QA			

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1.0 Introduction

The "Automatic Vertical Round Bottle Sticker Labelling Machine "is intended for the manufacturing of powder oral dosage form. The machine is used labeling on round bottle. It is capable for labeling 100 to 120 containers per minute depending on product & label size and filling head to achieve desired filled with assurance of product quality & safety.

2.0 Objective

Objective of this report is to assess the risk associated with the equipment "Automatic Vertical Round Bottle Sticker Labelling Machine" in pre assessment in the manufacturing facility of Cepha Oral Block of ……., in line with the guidance of the Risk Management manual of ……and ICH Q9.

3.0 Scope

The scope of this document is limited to the design, installation, operation, performance and safety of equipment "Automatic Vertical Round Bottle Sticker Labelling Machine" and define its failure mode at pre assessment in the manufacturing facility at …….

4.0 Risk assessment approach

Risk assessment is carried out as per FMEA (Failure mode effects analysis) method)

5.0 Responsibility

Quality Assurance
Engineering
Production
Quality Control
Store

6.0 Reference Documents

1. ICH Q9-Quality Risk Management

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Background

……..is intended to start manufacturing of powder oral facility at ……. Risk assessment is a part of corporate quality assurance. Pre Quality Risk assessment of "Automatic Vertical Round Bottle Sticker Labelling Machine" is done to check the system is capable of providing quality product throughout the life cycle of the drug product.

7.0 RISK RANKING PARAMETER

7.1 Rating parameters for Severity

Effect	Scale	Description
No effect	1	No effect on output
Very slight	2	Customer not annoyed
Slight	3	Slight
Minor	4	Minor effect on performance
Moderate	5	Moderate effect on performance
Significant	6	Partial failure but operable
Major	7	Product performance severely affected, but some operability and safe
Extreme	8	Very dissatisfied, product inoperable but safe
Serious	9	Potentially hazardous effect, time-dependent failure
Hazardous	10	Hazardous effect, safety related sudden failure

7.2 Rating parameters for Occurrence

Occurrence	Scale	Description
Almost never	1	Failure unlikely; history shows no failures
Remote	2	Rare number of historical failure
Very Slight	3	Very few failures likely
Slight	4	Few failures likely
Low	5	Occasional number of failures likely

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Occurrence	Scale	Description
Medium	6	Medium number of failures likely
Moderately High	7	Moderately high number of failures likely
High	8	High number of failures likely
Very High	9	Very high number of failures likely
Almost certain	10	Failure almost certain

7.3 Rating parameters for Detection control

Detection	Scale	Description
Almost certain	1	Proven detection methods with high reliability
Very High	2	Proven detection methods available
High	3	Detection tools have high chance of detecting methods
Moderately High	4	Almost certain not to detect failure
Medium	5	Detection tools have moderate chance of detecting defect
Low	6	Detection tools have a low chance of detecting failure
Slight	7	Detection tools may not detect failure
Very Slight	8	Detection tools will probably not detect failure
Remote	9	Detection tools most likely will not detect failure
Impossible	10	Failure not detected

Note: Individual contributory factor for each potential failure mode shall be rated. Other scale parameters may also be selected based on the process.

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8.0 ACCEPTANCE CRITERIA FOR RISK ASSESSMENT BY FMEA

Acceptance criteria for FMEA are as follows:

S.No.	RPN Rating	RPN Category	Action Status
1.	≥ 76	Critical	CAPA Required
2.	51 to 75	Major	CAPA Required
3.	26 to 50	Moderate	CAPA Required
4.	Up to 25	Minor	Not applicable

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9.0 PRE-RISK ASSESSMENT AS PER FMEA:

Name of facility/Utility/Equipment/Process/Operation: Automatic Vertical Round Bottle Sticker Labelling Machine

S. No.	Potential Failure Mode	Potential effect (s) of failure	Severity (S)	Potential cause/ Mechanism of failure	Occurrence (O)	Current Control	Detection (D)	RPN (S x O x D)	Recommended action	Responsibility and TCD	Action Results				
											Action taken	Severity	Occurrence	Detection	New RPN
1	Required Area (floor, Temperature, RH, Differential pressure) not proper for the automatic Vertical Round Bottle Sticker Labelling Machine	Area will not be suitable for proper functioning of Equipment.	6	No or less clarity of the product requirement and machine functionality.	3	Approved layout is in place with dimensions & required environmental condition	3	54	Care has to be taken during Area Qualification	Engineering ,QA, Production					

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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S. No.	Potential Failure Mode	Potential effect (s) of failure	Severity (S)	Potential cause/ Mechanism of failure	Occurrence (O)	Current Control	Detection (D)	RPN (S x O x D)	Recommended action	Responsibility and TCD	Action Results				
											Action taken	Severity	Occurrence	Detection	New RPN
2	Required parameter not defined in URS. URS not proper for system	Systems not receive suitable for proper output of quality with all parameter as per specification. Affect the product quality.	4	No or less clarity of the product requirement and machine functionality.	3	Preparation of URS before procurement of equipment is in place with all pre-specified parameter.	2	24	Current control measures are adequate	NA	NA	NA	NA	NA	NA
3	Required utilities (compressed air, electricity) are not available	Machine will not function as expected.	7	No or less clarity of the product requirement and machine functionality with respect to utility requirement.	2	URS is in place for system with all predefined requirement of utility like electricity, compressed air.	1	14	Current control measures are adequate	NA	NA	NA	NA	NA	NA

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S. No.	Potential Failure Mode	Potential effect (s) of failure	Severity (S)	Potential cause/ Mechanism of failure	Occurrence (O)	Current Control	Detection (D)	RPN (S x O x D)	Recommended action	Responsibility and TCD	Action Results				
											Action taken	Severity	Occurrence	Detection	New RPN
4	Wrong machine selection in terms of Dimension, capacity and output.	Installation will be affected if dimension is not considered. Output will also get affected if capacity is not considered.	6	No or less clarity of the machine.	2	URS is in place for dimension , capacity and rated output of the of the RMG	1	12	Current control measures are adequate	NA	NA	NA	NA	NA	NA
5	MOC and machine contact parts not meeting GMP requirement	Not meeting GMP requirements and product get affected.	7	No or less clarity of the machine contact part and MOC.	3	URS is in place for MOC (contact part should be of SS316 or 316L and non contact parts will be of SS304 and machine contact parts to fulfill GMP requirements. Gasket used shall be of food grade rubber.	1	21	Current control measures are adequate	NA	NA	NA	NA	NA	NA

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S. No.	Potential Failure Mode	Potential effect (s) of failure	Severity (S)	Potential cause/ Mechanism of failure	Occurrence (O)	Current Control	Detection (D)	RPN (S x O x D)	Recommended action	Responsibility and TCD	Action Results				
											Action taken	Severity	Occurrence	Detection	New RPN
6	Equipment not received with the safety measures.	Accident may happen.	10	No or less clarity about equipment	2	Requirement of Safety measures like interlocking for purging air, LID , Side guard, discharge port is defined in URS.	1	20	Current control measures are adequate	NA	NA	NA	NA	NA	NA
7	Required bottle (glass, HDPE) are not available	Machine will not function as expected.	10	No or less clarity of the product requirement and machine functionality with respect to bottle requirement.	2	URS is in place for system with all predefined requirement of bottle like glass, HDPE	1	20	Current control measures are adequate	NA	NA	NA	NA	NA	NA

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9.1 REVIEW OF RISK ASSESSMENT AS PER FMEA AFTER ACTION TAKEN:

Action Result					Remarks
Action Taken	Severity	Occurrence	Detectability	RPN	

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10.0 RISK CONTROL MEASURES

Investigation/ findings: *(an extra sheet can be used if space is insufficient)*

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Corrective Action: *(an extra sheet can be used if space is insufficient)*

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(Sign/Date)

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11.0 SUMMARY AND CONCLUSION REPORT FOR RISK ASSESSMENT

Summary:

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Conclusion: ……

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12.0 FINAL REPORT APPROVAL:

The final report shall be signed after identifying all the risks and critical control parameters. All the reports or documents have been attached to the respective report (if applicable).

Signature in the block below indicates that all the control measures taken are documented and have been reviewed and found to be acceptable.

Department	Name	Designation	Signature	Date
Quality assurance				
Production				
Quality control				
Utility				
Store				
Head-QA				