PRE RISK ANALYSIS FOR AUTOCARTONATOR

RISK ASSESSMENT

REPORT BY FMEA

Product/System/Equipment	**Autocartonator**
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			

PRE RISK ANALYSIS FOR AUTOCARTONATOR

1.0 Introduction

The "Autocartonator" is intended to use for packing of blister in unfolded carton with batch coding printing in the pharmaceutical sector is a huge need for a cartooning machine that minimize to the least human contact with the product and at the same time gives high output for its large volume products. It is a continuous motion, fully automatic horizontal cartooning machine which can attain a maximum speed of 150 carton per minute. This high speed is achieved by a specially designed rotary pick-up system for the carton from magazine. Also, its link up with the various blisters packing machine completely automates the packing process for the drug which was not possible so far with high output with assurance of product safety.

2.0 Objective

Objective of this report is to assess the risk associated with the equipment "Autocartonator" in pre assessment in the manufacturing facility of General 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 "Autocartonator" system 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
2. ……. guidance on Risk Assessment.

PRE RISK ANALYSIS FOR AUTOCARTONATOR

Background

…….. is intended to start manufacturing of semi solid oral facility at ……. Risk Assessment is a part of corporate quality assurance. Pre Quality Risk assessment of "Autocartonator" is done to check the system is capable of providing quality product throughout the life cycle of the drug product.

7.0 RISK RANKING PARAMETERS

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
Medium	6	Medium number of failures likely

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Occurrence	Scale	Description
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.

8.0 ACCEPTANCE CRITERIA FOR RISK ASSESSMENT BY FMEA

Acceptance criteria for FMEA are as follows:

S.No.	RPN Rating	RPN Category	Action Status
01.	≥ 76	Critical	CAPA Required
02.	51 to 75	Major	CAPA Required
03.	26 to 50	Moderate	CAPA Required
04.	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: Autocartonator

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) and APU unit with pre, fine filter unit not proper for the Autocartonator.	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 & equipment qualification	Engineering, A, Production					
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	N A	NA	N A	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
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 as electricity, compressed air.	1	14	Current control measures are adequate	NA	NA	N A	NA	N A	NA
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 Autocartonator.	1	12	Current control measures are adequate	NA	NA	N A	NA	N A	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 and non contact parts will be of SS304 and machine contact parts to fulfill GMP requirements.	1	21	Current control measures are adequate	NA	NA	N A	NA	N A	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	Interlock provision not available	Accident may happen.	10	No or less clarity about equipment safety measures.	2	Interlock provision is required defined in URS.	1	20	Current control measures are adequate	NA	NA	N A	NA	N A	NA
7	Equipment not received with the process safety measures.	Accident may happen.	10	No or less clarity about equipment safety measures.	2	Requirement of Safety measures like interlocking for Side guard alarm, emergency stop, alarm, Compressed air and Vacuum defined in URS.	1	20	Current control measures are adequate	NA	NA	N A	NA	N A	NA

PRE RISK ANALYSIS FOR AUTOCARTONATOR

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

Action Results					Remarks
Action Taken	**Severity**	**Occurrence**	**Detection**	**RPN**	

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)

PRE RISK ANALYSIS FOR AUTOCARTONATOR

11.0 SUMMARY AND CONCLUSION REPORT FOR RISK ASSESSMENT

Summary:

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Conclusion:

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PRE RISK ANALYSIS FOR AUTOCARTONATOR

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				
Engineering				
Store				
Head-QA				