POST 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			

POST 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 pharmaceuticals 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 post 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" and defines its failure mode at post assessment in the manufacturing facility at …….

4.0 Risk assessment approach

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

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.

POST RISK ANALYSIS FOR AUTOCARTONATOR

Background

…… is intended to start manufacturing of solid oral facility at ……. Risk assessment is a part of corporate quality assurance. Post 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
Moderately High	7	Moderately high number of failures likely

Occurrence	Scale	Description
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
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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POST RISK ANALYSIS FOR AUTOCARTONATOR

9.0 POST 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	Design Qualification document is received inadequate.	Equipment may not function as desired.	4	No or inadequate clarity (Knowledge) in preparation of URS.	3	URS is prepared by experienced personnel with the help of engineering, QA & department Head. Well experienced Personnel from QA, Engineering & user department will verify DQ against URS.	2	24	Current control measures are adequate.	NA	NA	NA	NA	NA	NA
		cGMP requirement will not meet.	7		3		1	21		NA	NA	NA	NA	NA	NA
		Safety measures with respect to operator and environment will not be clear.	4		3		2	24		NA	NA	NA	NA	NA	NA
		Major components list will be missed out.	6		2		2	24		NA	NA	NA	NA	NA	NA

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											Action taken	Severity	Occurrence	Detection	New RPN
2	Design Qualification document is received inadequate.	Requirement of utilities (power and compressed air) will not be clear.	3	No or inadequate clarity (Knowledge) in preparation of URS.	4	URS is prepared by experienced personnel with the help of engineering, QA & department Head. Well experienced Personnel from QA, Engineering & user department will verify DQ against URS.	2	24	Current control measures are adequate	NA	NA	NA	NA	NA	NA
		Functional design specification will not be available.	4		3		2	24		NA	NA	NA	NA	NA	NA
		Generally assembling diagram will not be clear	4		4		1	16		NA	NA	NA	NA	NA	NA
		Instrument list connected with equipment will be missing	4		3		2	24		NA	NA	NA	NA	NA	NA

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											Action taken	Severity	Occurrence	Detection	New RPN
3	Design Qualification document is not checked and verified properly.	Document verification related to design verification, cGMP requirement, Instrument & control verification, components verification, utility verification & safety verification will not be appropriate.	4	Inadequate knowledge or inadequate training to all concerned.	3	Well experienced Personnel from QA, Engineering & user department will verify DQ against URS.	2	24	Current control measures are adequate.	NA	NA	NA	NA	NA	NA
4	Installation Qualification document is inadequate.	Inadequate Installation of equipment.	7	Inadequate information in IQ.	3	Interpretation of URS along with DQ. SOP is in place for verification of IQ document.	1	21	Current control measures are adequate.	NA	NA	NA	NA	NA	NA
		Identification of major components will be missing	6	Inadequate information in IQ.	2	Interpretation of URS along with DQ. SOP is in place for verification of IQ document.	2	24	Current control measures are adequate.	NA	NA	NA	NA	NA	NA

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											Action taken	Severity	Occurrence	Detection	New RPN
5	Installation Qualification document is inadequate.	No or inadequate clarity on equipment / documents required for completion of IQ.	3	Inadequate information in IQ.	3	Interpretation of URS along with DQ. SOP is in place for verification of IQ	2	18	Current control measures are adequate	NA	NA	NA	NA	NA	NA
6	Calibrated Measuring equipment not available at site. (Multi meter, spirit level).	Installation will be improper, equipment will not perform as intended	6	Inadequate training.	4	Qualification team will ensure Physically for the availability of equipments before execution of IQ.	1	24	Current control measures are adequate.	NA	NA	NA	NA	NA	NA
7	Reference document not available at site during IQ. (FDS, PLC FDS, GA and electrical drawing, installation & Operational manual, Material chart with test certificate & Manual).	Installation will be improper, Equipment will not perform as intended.	6	Inadequate knowledge for verification of reference documents on receipt.	4	Qualification team will ensure Physically for the available of documents before execution of IQ.	1	24	Current control measures are adequate.	NA	NA	NA	NA	NA	NA

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											Action taken	Severity	Occurrence	Detection	New RPN
8	Equipment name plate not available during IQ.	Equipment will not be identified.	4	Equipment name plate not provided by vendor.	3	Procedure is in place for verification during IQ.	2	24	Controlled measures are in place.	NA	NA	NA	NA	NA	NA
9	Instrumentation & calibration check not performed.	IQ will not be performed.	5	Inadequate Knowledge or training to concern personnel.	3	Procedure is in place for verification during IQ.	1	15	Controlled measures are in place.	NA	NA	NA	NA	NA	NA
10	Operational document is inadequate.	Inadequate Operation of equipment.	6	Inadequate information in OQ.	4	SOP is in place for verification of OQ Protocol.	1	24	Controlled measures are in place.	NA	NA	NA	NA	NA	NA
11	IQ not completed prior to OQ.	OQ Cannot be proceeding.	6	Incomplete documentation. Installation not completed.	4	SOP is in place to perform OQ after successful completion of IQ.	1	24	Controlled measures are in place.	NA	NA	NA	NA	NA	NA
12	Prequalification requirement not checked during OQ. (Tools are not removed from the equipment).	Accident may happen.	10	Inadequate knowledge or safety measures are not followed.	2	Activity will be performed by Trained personnel.	1	20	Controlled measures are in place.	NA	NA	NA	NA	NA	NA

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											Action taken	Severity	Occurrence	Detection	New RPN
13	Emergency "STOP" button not released.	Equipment will not run.	6	Inadequate knowledge.	4	Procedure is in place for verification during OQ.	1	24	Controlled measures are in place.	NA	NA	NA	NA	NA	NA
14	External equipment is not disconnected.	Accident may happen.	10	Inadequate knowledge or safety measures are not followed.	2	Activity will performed by trained personnel. Procedure is in place for verification during OQ.	1	20	Controlled measures are in place.	NA	NA	NA	NA	NA	NA
15	Equipment operation verification not done. (Noise level).	Equipment will not perform as intended.	10	Inadequate knowledge/training for operating the equipment.	2	Procedure is in place for verification during OQ.	1	20	Controlled measures are in place.	NA	NA	NA	NA	NA	NA
16	Equipment control functions & alarm verification test not done.	Equipment will not function as desired.	7	Inadequate knowledge/training for operating the equipment.	3	Procedure is in place for verification during OQ.	1	21	Controlled measures are in place.	NA	NA	NA	NA	NA	NA
17	Adequate safety features for men and material not provided with the equipment.	Accident may happen.	10	Inadequate knowledge.	2	Procedure is in place for verification during IQ & OQ.	1	20	Controlled measures are in place.	NA	NA	NA	NA	NA	NA

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											Action taken	Severity	Occurrence	Detection	New RPN
18	Equipment control functions verification test not done.	Selection of appropriate mode like Manual, Auto, will not be possible.	8	Inadequate knowledge/training for operating the equipment.	3	1. Verified in Operational checks during OQ.	6	144	SOP will be prepared for proper selection recipe for product, Maintenance, wash.	Production,					
19	Equipment control functions verification test not done.	System will not give any alarm during malfunctioning.	6	System runs in Manual Mode.	4	Activity will performed by trained personnel.	1	24	System should not run in manual mode after validation, accordingly SOP will be prepared.	NA	NA	NA	NA	NA	NA
20	Equipment is not assembled after cleaning, preventive maintenance, and break down, calibration.	Accident may happen. Equipment not functioned as expected.	10	Inadequate knowledge/training for operating the equipment.	2	Procedure is in place for proper assembling after properly cleaning, preventive maintenance, calibration.	1	20	Control measures are in place.	NA	NA	NA	NA	NA	NA

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											Action taken	Severity	Occurrence	Detection	New RPN
21	Product designing is not done considering current equipment design and capacity.	Performances of equipment will not guarantee. Product quality may get affected.	6	No or inadequate clarity about equipment design and capacity.	3	Performance qualification will be carried out on equipment considering Min. & Max. Capacity & design.	1	18	Control measures are in place.	NA	NA	NA	NA	NA	NA
22	Process monitoring is not done.	Performance of the equipment will not be guaranteed.	8	Inadequate knowledge/training.	3	Process validation & APR will cover the monitoring part.	1	24	Control measures are in place.	NA	NA	NA	NA	NA	NA
23	Process validation guidance is not clear (sample withdrawal).	Performance of the equipment will not be guaranteed.	8	Inadequate knowledge/training.	2	Process validation protocol will cover the sampling location.	1	16	Control measures are in place.	NA	NA	NA	NA	NA	NA
24	Equipment is not cleaned properly.	Product will contaminate.	8	Cleaning procedure is not followed correctly.	2	Line clearance & cleaning procedure is in place.	1	16	Control measures are in place.	NA	NA	NA	NA	NA	NA

POST 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	

POST RISK ANALYSIS FOR AUTOCARTONATOR

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)

POST RISK ANALYSIS FOR AUTOCARTONATOR

11.0 SUMMARY AND CONCLUSION REPORT FOR RISK ASSESSMENT

Summary:……..

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Conclusion:

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POST 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				