PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN

RISK ASSESSMENT

REPORT BY FMEA

Product/System/Equipment	**AUTOCOATER**
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 "Auto-coater" is intended to use for efficient film coating of tablets in closed condition. The tablet cores are loaded into the perforated pan through front opening of pan. The tablet cores are first pre-warmed with drying air through the bed. The tablets are tumbled and mixed with the aid of baffles and the rotating pan. The cores are spread upon with the film forming polymers by battery of air ,automatized spray gun .the spray is delivered concurrently with a drying air for affecting rapid impingement coalescing and formation of film with assurance of product safety.

2.0 Objective

Objective of this report is to assess the risk associated with the equipment "Auto-coater" in post 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 "Auto-coater" 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. ……pharmaceuticals guidance on Risk assessment.

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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 "Auto-coater" 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

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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
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 POST-RISK ASSESSMENT AS PER FMEA:

Name of facility/Utility/Equipment/Process/Operation: Auto-coater

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 received is inadequate.	Equipment may not function as desired.	4	No or inadequate clarity (Knowledge) in preparation of URS.	3	1. URS is prepared by experienced personnel with the help of engineering, QA & department Head. 2. 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
		c-GMP requirement will not met	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
		Clarity on P n. diagram will not be clear	3		3		2	18		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
	Design Qualification document received is 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
		Electrical General 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
2	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
3	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

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											Action taken	Severity	Occurrence	Detection	New RPN
		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
		No or inadequate clarity on equipment / documents required for completion of IQ.	3		3		2	18		NA	NA	NA	NA	NA	NA
4	Calibrated Measuring equipment not available at site.(multimeter, spirit level, Tachometer)	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

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											Action taken	Severity	Occurrence	Detection	New RPN
5	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
6	MOC verification not done during IQ (For contact and non contact parts)	Product may gets contaminated	7	MOC Test certificate not provided by vendor. Molybdenum Kit Not available	4	Procedure is in place for verification during IQ.	2	56	Molybdenum kit to be procured	Engine ering					
7	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

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											Action taken	Severity	Occurrence	Detection	New RPN
8	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
9	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
10	IQ not completed prior to OQ	OQ Cannot be proceed	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
11	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
	Emergency "STOP" button not released.	Equipment will not run	6	Inadequate knowledge	4	Procedure are in place for verification during OQ	1	24	Controlled measures are in place	NA	NA	NA	NA	NA	NA
	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 are in place for verification during	1	20	Controlled measures are in place	NA	NA	NA	NA	NA	NA
12	Temperature sensors are not calibrated	Accuracy of temperature will not be achieved	7	Inadequate knowledge/training	3	Procedure are in place for verification during OQ	1	21	Controlled measures are in place	NA	NA	NA	NA	NA	NA
13	Equipment operation verification not done. (Noise level).	Equipment will not perform as intended	10	Inadequate knowledge/training for operating the equipment.	2	Procedure are in place for verification during OQ	1	20	Controlled measures are in place	NA	NA	NA	NA	NA	NA
14	Filters(coarse,pre ,fine,hepa,exhaus t filters are not available in APU unit	Product & environment will be contaminated	10	Inadequate knowledge/training	2	Procedure are 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
15	APU unit is not functioning	Product & environment will be contaminated, Desired drying temperature will not achieved	10	Inadequate knowledge/training	3	Procedure are in place for verification during OQ	1	30	Controlled measures are in place, Performance checks to be verified during PQ.	Engineering, QA, Production,					
16	Equipment control functions, interlocks & alarm verification test not done.	Equipment will not function as desired.	7	Inadequate knowledge/training for operating the equipment.	3	Procedure are in place for verification during OQ	1	21	Controlled measures are in place	NA	NA	NA	NA	NA	NA
	Adequate safety features for men and material not provided with the equipment	Accident may happen	10	Inadequate knowledge	2	Procedure are in place for verification during IQ & OQ	1	20	Controlled measures are in place	NA	NA	NA	NA	NA	NA
	Flame proof motors,& not provided	Accident may happen	10	Inadequate knowledge	2	Procedure are in place for verification during IQ & OQ	1	20	Controlled measures are in place						

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											Action taken	Severity	Occurrence	Detection	New RPN
	Equipment control functions verification test not done.	Recipe preparation will not be possible	8	Inadequate knowledge/training for operating the equipment.	3	Procedure for Preparation of Recipe is available in operational manual	7	168	SOP will be prepared for preparation of Recipe	Production,					
		Equipment will not be under password protection	8	Recipe is not prepared through password protection	4	Procedure for Preparation of Recipe is available in operational manual	6	192	SOP will be prepared for preparation of password protection	Production,					
		Selection of appropriate mode like Manual, Auto, Recipe, Maintenance, wash will not be possible	8	Inadequate knowledge/training for operating the equipment	3	Verified in Operational checks during OQ.	6	144	SOP will be prepared for proper selection recipe for product, Maintenance, wash	Production,					
		System will not give any alarm during malfunctioning.	6	System run 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

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											Action taken	Severity	Occurrence	Detection	New RPN
17	Equipment is not assembled after cleaning, preventive maintenance, 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
18	Recipe not prepared for Product, Wash, and maintenance cycle.	Consistent performance of equipment will not be possible	6	Inadequate knowledge/training for operating the equipment	4	Procedure for Preparation of Recipe is available in operational manual	5	120	Sop will be prepared for recipe preparation for Product, Wash, and maintenance cycle.	Produc tion,					
19	Major changes done without any documentation	Performances of equipment will not guaranteed. Product quality may get affected	6	Inadequate knowledge/training	3	Change control Sop is in place	1	18	Control measures are in place.	NA	NA	NA	NA	NA	NA

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											Action taken	Severity	Occurrence	Detection	New RPN
20	Product designing is not done considering current equipment design and capacity	Performances of equipment will not guaranteed. 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
21	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
22	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
23	Equipment is not cleaned properly	Product will contaminated	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

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											Action taken	Severity	Occurrence	Detection	New RPN
24	Temperature Sensor are not calibrated	Accuracy of temperature will not achieved	6	Inadequate knowledge	2	Procedure are in place for verification during OQ	1	12	Control measures are in place.	NA	NA	NA	NA	NA	NA
26	Atomization in is not proper	Product will not meet the specification	7	Insufficient amount of air is available. Improper dosing Peristaltic pump not properly working.	5	Procedure is in place for verification during OQ	2	70	PQ protocol for checking of automization & preventive maintenance schedule will be prepared check proper function of peristaltic pump .	QA, Production, engineering,					
27	Wet scrubber is not functioning properly.	Negative pressure is not maintained, expulsion of dust and coating resins, CFM is not maintained	8	Inadequate knowledge/training, Pre-Filter chocked.	4	Procedure are in place for verification during OQ, Activity will performed by Trained personnel, filter should be cleaned periodically.	2	64	Control measures are in place.						

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											Action taken	Severity	Occurrence	Detection	New RPN
28	Spray guns are not properly working	Affected on product quality	7	Inadequate knowledge/training	3	Procedure is in place for verification during OQ, Activity will performed by Trained personnel.	1	21	Control measures are in place.	NA	NA	NA	NA	NA	NA
29	Inlet air blower and exhaust air blower are not properly working.	Affected on product quality	7	Inadequate knowledge/training, Preventive maintenance not followed periodically	3	Alarm message of CFM, negative pressure on HMI, Preventive maintenance schedule will be followed.	1	21	Control measures are in place	NA	NA	NA	NA	NA	NA
30	Baffle arrangements are not working.	Tablets are not tumbled well, improper coating.	4	Inadequate knowledge	3	Procedure are in place for verification during OQ, Activity will performed by Trained personnel.	2	24	Control measures are in place	NA	NA	NA	NA	NA	NA
31	WIP(wash in place) is not properly done (Water not drained thoroughly)	Water comes through inlet and out let affects the product.	4	Inadequate knowledge/training and information.	3	Activity will performed by Trained personnel.	2	24	Control measures are in place	NA	NA	NA	NA	NA	NA

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											Action taken	Severity	Occurrence	Detection	New RPN
32	Pan perforation chocked	Affects drying of tablets	7	Inadequate knowledge/training and information about cleaning	3	Activity will performed by Trained personnel.	1	21	Control measures are in place	NA	NA	NA	NA	NA	NA
33	Improper hardness of gasket	Product quality contaminated, arm seal not proper and negative pressure not maintained	7	No or inadequate Knowledge	3	Procedure is in place for verification during qualification	3	63	Vendor has to provide test certificate mentioning hardness.	Production, QA,					

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

Action Results					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				
Engineering				
Store				
Head-QA				