PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MANUFACTURING OF OSD

Reference Document No.: | **Risk Assessment No.:** …….

Name of Facility / Equipment / Utility / System / Activity / Procedure / Unit Operation for: Coating Manufacturing (OSD)

Date Of Quality Risk Assessment:

S. No.	Item / Function	Potential Failure Mode	Potential Effect of Failure (Effect)	Potential Cause/ Mechanism of Failure	Current Control	Reference	Risk with Current control Measure				Recommended Actions (if any)	Risk after control measure			RPN (S*O*D)
							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
1.	**Coating**	Probability of improper working of machine	Contamination & product failure	➢ Coating machine is not qualified. ➢ Coating machine is not working properly. ➢ Preventive maintenance schedule is not available & followed. ➢ Activity is performed by untrained personnel. ➢ All washing process not done on controlled area or area not specified for washing of equipments. ➢ Procedure for cleaning is not available and followed	➢ Coating machine is qualified. ➢ Coating machine is working properly & preventive maintenance schedule available & followed. ➢ Activity is performed by the trained personnel. ➢ Calibration done of all gauzes and other on routine basis ➢ All washing process done in controlled area. ➢ Dedicated area provided for washing of equipments. ➢ Procedure for cleaning is available and followed	**Qualification Protocol** **Cleaning procedure** **SOP**	2	1	4	8	NA	NA	NA	NA	NA
		Probability of microbial contamination in product through machine parts	Product failure	➢ If machine parts are not cleaned ➢ If untrained persons performing activity. ➢ Procedure in not available for handling	➢ Machine parts are cleaned before using in process. Procedure of handling of change parts is available. ➢ Only trained persons performed all the activity.	**SOP**	4	1	2	8	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
				of Machine Parts. ➢ Storage of machine parts	➢ Verification of cleaning of machine parts by QA. ➢ SOP for cleaning & storage of machine change parts accessories.										
	Coating	Probability of microbial contamination in product though coating solution	Product failure	➢ If equipment used for preparing coating solution not cleaned. ➢ If untrained person performing activity. ➢ Solution not filter before using in coating ➢ Persons doing work in coating area are not qualified ➢ Door interlocking is not present to prevent cross contamination ➢ Unidirectional Men Material Movement / Flow are not maintained.	➢ Equipment are cleaned Verification of cleaning is bone by QA. ➢ Only trained person performed all the activity. ➢ Solution filtered through muslin cloth or as define in the BMR of respective procedure. ➢ All persons doing work in coating area are trained. ➢ Door interlocking is present to prevent cross contamination ➢ Unidirectional Men Material Movement / Flow are provided.	Personal Training Record	4	1	3	12	NA	NA	NA	NA	NA
		Probability of defects in coated tablets	Market Complaint & defects into the product	➢ Proper setting of machine is not done. ➢ If spray gun and coating pan not checked. ➢ If In-process not done	➢ Initial setting parameter is checked by the Operator and Production Personnel for proper setting of the machine. Proper cleaning of machine parts before every	Visual Inspector Qualification	4	1	4	16	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
				at regular interval by trained person. ➢ Procedure is not available for controlling visual defects.	batch. ➢ Initial parameter also verified by QA Personnel. ➢ Only trained person performed the in- process. ➢ Regular in-process checks are performed by the production and QA. ➢ Visual checks performed in different time intervals.	In process checks procedure									
	Coating	Probability of weight variation	Weight variation and product failure during QC testing	➢ Tablets not checked for tablet weight. ➢ In-process checks not performed. ➢ Weight variation not performed. ➢ Activity is performed by untrained personnel. ➢ Balance is not calibrated ➢ Proper setting of machine is not done by operator initially.	➢ Weight Variation of all the parameters at initially and defined frequency is performed for tablets by trained personnel as it is part of BMR. ➢ In-process checks performed at frequency defined in BMR. ➢ Weight variation performed at regular frequency. ➢ Activity is performed by trained personnel. ➢ Daily verification and monthly calibration is in practice. ➢ Calibrated weighing balance is used for weighing,	BMR Weighing verification procedure	4	1	4	16	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
					➢ Machine setting parameters checked by operator & production personnel before starting the Coating activity.										
	Coating	Probability of Product Mix up (Quarantine Area)	Product mix up	➢ Batches are not segregated with proper status labeling. ➢ Labeling not done in the container in which product is placed. ➢ Unauthorized/untrained entry in quarantine area. ➢ Lock and key arrangement not available for access of unauthorized person entry.	➢ Pallets are provided for segregation of different batches and different products. And also status label put on all carats ➢ Access of authorized persons only is there in quarantine area. ➢ Logbooks are maintained for filled product/Good products inwards and outwards of different products. ➢ Quarantine room shall be lock & key arrangement & Access of authorized persons only is there in quarantine area	Authorized Persons List Log books	4	1	2	8	NA	NA	NA	NA	NA

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Reference Document No.:	Risk Assessment No.: …….

Where: S=Severity; O=Occurrence Probability; D=Detection

Remarks (if any):

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Quality Risk Management Team			Reviewed By Head Operations Sign & Date	Approved By Head QA Sign & Date
Name	Department	Sign & Date		

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QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

Name of Facility / Equipment / Utility / System / Activity / Procedure / Unit Operation:	MANUFACTURING

S. No.	Recommended Action	Responsible Person	Target Date of Completion

Verification of Action Plan:

All the above agreed actions completed, Not Completed.

(*incase any recommendations Not completed, to be tracked through CAPA System)

Remarks (if any):

_____

_____

Verified By
QA
Sign & Date

Approved By
Head QA
Sign & Date