PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR COMPRESSION OF OSD

Reference Document No.:	**Risk Assessment No.:** …….
Name of Facility / Equipment / Utility / System / Activity / Procedure / Unit Operation for: Compression (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.	**Compression**	Probability of improper working of machine	Contamination & product failure	➢ Compression machine is not qualified. ➢ Compression machine is not working properly. ➢ Preventive maintenance schedule is not available & followed. ➢ Activity is performed by untrained personnel. ➢ Defects not checked for its appearance or shape/size ➢ Change parts like hopper, chute are not cleaned. ➢ Procedure is not available for Inspection, Handling, Polishing and Destruction of Punches and Dies	➢ Compression machine is qualified. Calibration done of all gauzes and other on routine basis ➢ Compression machine is working properly & preventive maintenance schedule available & followed. ➢ Compression machine checked before taking product as per provided check list. ➢ Activity is performed by the trained personnel. ➢ Visual checks in different time interval for visual defects. ➢ Change parts like hopper, chute are cleaned after completion of batch manufacturing activity. And rinse water sample send to QC department for analysis. ➢ Procedure is available for	Qualification Protocol SOP	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	
					Inspection, Handling, Polishing and Destruction of Punches and Dies										
		Probability of defects in compressed tablets	Market Complaint	➢ Proper setting of machine is not done. ➢ If compression machine not checked. ➢ Non availability of metal detector. ➢ Punch not cleaned properly by operator ➢ In process or machine run by untrained persons. ➢ If In-process not done at regular interval by trained person. ➢ Compression machine is not qualified	➢ Initial setting parameter is checked by the Operator and Production Personnel for proper setting of the machine before starting batch. ➢ Initial parameter also verified by QA Personnel. ➢ SOP for operation of metal detector is available. ➢ Proper cleaning of machine parts before every batch. ➢ Only trained person performed the in- process. ➢ Regular in-process checks are performed by the production and QA. ➢ Compression machine is qualified	SOP Qualification Protocol	4	1	3	12	NA	NA	NA	NA	NA

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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:	Compression (OSD)

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