PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR VISUAL INSPECTION FOR OSD

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

Name of Facility / Equipment / Utility / System / Activity / Procedure / Unit Operation for: Visual Inspection (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.	**Visual Inspection**	Probability of mix-up of Rejected tablets in Good tablets Container	Product Failure / Market complaint	➢ Tablet/capsule Inspection machine is not qualified. ➢ Visual Inspectors are not trained for sorting of tablets/Capsule. ➢ Status label put on each container “Ready for packing”. ➢ Unauthorized entry in quarantine area. ➢ Light intensity is not suitable for the activity. ➢ Inspection activity is performed by untrained personnel. ➢ Procedure not available for process of inspection checks	➢ Tablet/capsule Inspection machine is qualified. ➢ Visual Inspectors are trained for sorting of tablets/Capsule. ➢ Medical Examination also performed for inspectors. ➢ Status label put on each container “Ready for packing”. Lid of container closed and properly tight with cable tie ➢ All drums are placed pallets wise affix status label “Ready for packing” ➢ Only of authorized persons access is there in inspection area ➢ Light intensity is suitable for the activity. ➢ Inspection activity is performed by trained personnel. ➢ Procedure available for	Qualification Protocol SOP	4	1	3	12	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
				during tablet packing	process of inspection checks during tablet packing										
		Probability of storage of sorted tablets in unclean container	Chance of Contamination	➢ If Clean Container not available for storage of inspected tablets. ➢ Procedure not available for Cleaning of Container.	➢ Dedicated Container provided for storage of inspected tablets. ➢ Cleaning procedure is available & cleaning log also available for Cleaning of Container.	SOP	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:	Visual Inspection

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