PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR LABELING OF OSD

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

Name of Facility / Equipment / Utility / System / Activity / Procedure / Unit Operation for: Labeling (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.	**Labeling**	Mixing of packing material in secondary packing area	Products mix up.	➢ Two different product of packing material placed in same area /Line. ➢ Procedure is not available for verification of packing material after dispensing or packing material keeping in Staging area. ➢ Status labeling not in practice. ➢ Separate area not provided. ➢ Material not stored properly. ➢ Activity is performed by untrained personnel.	➢ Only one product packing material kept in Day Store at a time. ➢ One product & one batch taken at a time in packing area ➢ Procedure is available for verification of packing material after dispensing or packing material keeping in Staging area. ➢ Status labeling is in place. ➢ Dedicated Day store is provided for storage of Material line wise. ➢ Unidirectional flow is provided for the material movement. ➢ In case of use of extra material, Packaging Material taken in cubical only after verification from QA. ➢ All packing activity is performed by trained	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	
					personnel.										
	Labeling	Probability of mix up of stereos during product change over	Process failure and market complaint and direct impact on patient health	➢ If handling of stereos not proper. ➢ Written Procedure not available. ➢ Personnel handling stereo not trained. ➢ Lock & key system not available for keeping stereos. ➢ Procedure of Destruction of stereos not available.	➢ SOP for handling of Stereo is available & followed. ➢ One product issuance procedure is in practice. ➢ All stereo is handled by trained personnel. ➢ Destruction activity is performed by trained personnel in presence of QA Person. ➢ Lock & Key arrangement is available for storage of Stereo. ➢ Destruction of stereos after completion of batch done by QA persons only.	SOP	4	1	4	16	NA	NA	NA	NA	NA
		Probability of Wrong Proof Sign	Market Complaint & Product identification failure	➢ Coding style and price not as per provided list. ➢ Price list updated version not present in packing hall area or its designated place. ➢ Finished product price list not available in packing hall. ➢ SOP for finished product prices list is not	➢ Pre-Printed matter / specimen verified as per maintained coding style and price list as provided. ➢ Verification of specimen from QA after product check. ➢ Proof of coding matter is signed after complete verification from BMR & price List.	SOP	4	1	4	16	NA	NA	NA	NA	NA

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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	
				available& followed. ➢ Line clearance procedure not followed.	➢ Update price list is issued by QA after retrieval of supersede version ➢ In process checks also performed initially & at defined interval. ➢ Line clearance is followed before start of the activity. ➢ Procedure is available for Line clearance & followed properly.										
	Labeling	Probability of Packing of unprinted strips/carton with un-Coded strips / Carton	Market Complaint & improper identification	➢ If inspection is not performed. ➢ Activity is performed by untrained personnel. ➢ In-process checks not performed at defined intervals. ➢ Challenge test in case of blister machine is not performed at defined frequency.	➢ 100% inspection of printed packing strips/carton is performed. ➢ All packing activity is performed by trained personnel. ➢ In-process checks performed at defined intervals by Production & Quality Assurance Personnel. ➢ Challenge test of blister machine is part of SOP.	Batch Manufacturing Record	4	1	4	16	NA	NA	NA	NA	NA
		Variation in Quantity during Packing Operation	Market Complaint	➢ Inspection is not performed. ➢ Activity is performed by untrained personnel. ➢ Camera Challenge test	➢ 100% Visual inspection is performed. ➢ Packing activity is performed by trained personnel.	BPR SOP	4	1	2	8	NA	NA	NA	NA	NA

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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	
	Labeling			is not performed ➢ Weighing Process is not performed. ➢ Balance Verification / Calibration is not performed ➢ Procedure is not available for Weighing of Shipper	➢ Camera Challenge test is performed. ➢ All packed shipper are checked for weight in BPR ➢ Balance Verification / Calibration activity is performed on defined frequency. ➢ Procedure is available for Weighing of Shipper										

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

QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

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

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