PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR STORAGE & DISPATCH OF FINISHED GOODS

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

Name of Facility / Equipment / Utility / System / Activity / Procedure / Unit Operation for: Storage& dispatch of Finished Goods	**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.	**Storage& dispatch of Finished Goods**	Probability of improper Storage of Finished Goods	Product Failure	➢ Space is not provided for storage of Finished Goods. ➢ Temperature Monitoring is not performed. ➢ Racking System is not provided for proper storage of material with proper status labeling. ➢ Procedure is not available of transfer of Finished Goods to FG Store	➢ Dedicated Finished Goods Storage Area is provided. ➢ Temperature Monitoring is performed on regular basis. ➢ Racking System is provided for proper storage of material with proper status labeling. ➢ Procedure is available & followed of transfer of Finished Goods to Finished Goods Store.	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:	Storage& dispatch of Finished Goods

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