



# 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.:

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	<ul style="list-style-type: none"> <li>➤ Space is not provided for storage of Finished Goods.</li> <li>➤ Temperature Monitoring is not performed.</li> <li>➤ Racking System is not provided for proper storage of material with proper status labeling.</li> <li>➤ Procedure is not available of transfer of Finished Goods to FG Store</li> </ul>	<ul style="list-style-type: none"> <li>➤ Dedicated Finished Goods Storage Area is provided.</li> <li>➤ Temperature Monitoring is performed on regular basis.</li> <li>➤ Racking System is provided for proper storage of material with proper status labeling.</li> <li>➤ Procedure is available &amp; followed of transfer of Finished Goods to Finished Goods Store.</li> </ul>	SOP	4	1	3	12	NA	N A	N A	NA	NA

**Note: Action shall be taken if Risk Priority Number is more than 64.**



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

Remarks (if any):

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):

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Verified By  
QA  
Sign & Date

Approved By  
Head QA  
Sign & Date