





**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**FAILURE MODE EFFECT ANALYSIS FOR COATING PROCESS OF LEVOFLOXACIN TABLETS**

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	
		mention in validation protocol.	coating.		Production.										

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

**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**

<b>Name of Facility / Equipment / Utility / System / Activity / Procedure / Unit Operation:</b>	<b>Coating Process</b>
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<b>S.No.</b>	<b>Recommended Action</b>	<b>Responsible Person</b>	<b>Target Date of Completion</b>

**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**