PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR BATCH RELEASE

Reference Document No.:	**Risk Assessment No.:**
Name of Facility / Equipment / Utility / System / Activity / Procedure / Unit Operation for: Batch Release	**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.	**Batch Release**	In-complete analytical records and QA release documentation	System failure/ Market Complaint	➢ SOP not available for review of analytical records ➢ SOP not available for batch release	➢ SOP is available for review of analytical records ➢ For Batch release Only QA Head or in the absence of QA Head, Deputed person is Authorized to release the Batch ➢ SOP is available for review and batch release	SOP	4	1	4	16	NA	NA	NA	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):

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_____

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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:	Batch release

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