QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR BATCH RELEASE (OSD)

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

Name of Facility / Equipment / Utility / System / Activity / Procedure / Unit Operation for: Batch release (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.	**Batch release**	In-complete analytical records and QA release documentation	System failure/ Market Complaint	➤ No SOP for review of analytical records ➤ No SOP for batch release	➤ SOP for review of analytical records ➤ Only QA Head or in the absence of QA Head Deputed person is Authorized to release the Batch ➤ SOP for review batch release	SOP	4	1	4	16	NA	NA	NA	NA	NA

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

Remarks (if any):

QUALITY RISK ASSESSMENT & MITIGATION PLAN
FAILURE MODE EFFECT ANALYSIS FOR BATCH RELEASE (OSD)

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

_____

_____

_____

Quality Risk Management Team			Reviewed By Head Operations Sign & Date	Approved By Head QA Sign & Date
Name	Department	Sign & Date		

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR BATCH RELEASE (OSD)

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

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