PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR EXTERNAL PREPARATION IN MANUFACTURING FACILITY

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

Name of Facility / Equipment / Utility / System / Activity / Procedure / Unit Operation for: Transfer of Scrap	**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.	**Transfer of scrap**	Probability of contamination	Contamination & cross contamination	➢ Procedure is not available of handling and transfers of scrap ➢ Procedure is not available for Operation and Cleaning of scrap transfer Pass Box	➢ Procedure is available & followed for handling and transfers of scrap ➢ Procedure is available & followed for Operation and Cleaning of scrap transfer Pass Box	SOP	4	1	4	16	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:	Transfer of scrap

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