PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR BLENDING OF OSD

Reference Document No.:	**Risk Assessment No.:** …….
Name of Facility / Equipment / Utility / System / Activity / Procedure / Unit Operation for: Blending (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.	**Blending**	Probability of improper cleaning	Contamination & product failure	➢ Blender is not qualified. ➢ Blender is not working properly. ➢ Preventive maintenance schedule is not available & followed. ➢ Activity is performed by untrained personnel. ➢ All washing process not done on controlled area.	➢ Blender is qualified. ➢ Blender is working properly & preventive maintenance schedule available & followed. ➢ Blender checked daily as per provided check list. ➢ Activity is performed by the trained personnel. ➢ All washing process done on controlled area.	Qualification Protocol	4	1	2	8	NA	NA	NA	NA	NA
		Probability of improper working of blender	False result	➢ Blender is not qualified. ➢ Blender is not working properly. ➢ Preventive maintenance schedule is not available & followed. ➢ Activity is performed by untrained personnel.	➢ Blender is qualified. ➢ Blender is working properly & preventive maintenance schedule available & followed. ➢ Blender checked daily as per provided check list. ➢ Activity is performed by the trained personnel.	Qualification Protocol	4	1	3	12	NA	NA	NA	NA	NA
		Probability of microbial contamination in product through	Product failure	➢ If machine parts are not cleaned properly. ➢ If untrained persons performing activity. ➢ Procedure in not	➢ Verification of cleaning of machine parts by QA. ➢ Only trained persons performed all the activity. ➢ Procedure of handling of	**SOP**	4	1	4	16	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
		machine parts		available for handling of Machine Parts. ➢ Cleaning of change parts not done properly	change parts is available. ➢ Cleaning of change parts done properly										
	Blending	Variation in particle size distribution	Poor compaction properties ,poor flow of granules , Poor homogeneity.	➢ Variable granulation end point ➢ Incorrect equipment ➢ Wrong screen sizes used ➢ Person not trained to performed the activity	➢ Proper screen size taken during milling and sifting process as per BMR ➢ Granulation done as per BMR instruction and as per SOP of equipment and area. ➢ Only trained persons performed all the activity.	All SOP of Manufacturing Area	4	1	2	8	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:	Blending

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