



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ANALYSIS STUDY FOR MANUFACTURING OF DRY SYRUP FILLING MACHINE & AREA

S.No.	Item/ Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference document No.	S	O	D	Risk Priority Num ber (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxOxD
1.	The status of the dry syrup filling machine and area is stated and reported as clean, whereas yellow and white stains can be easily seen on the equipment and in the area.	Cleaning procedure of the dry syrup filling machine.	Contamination/ cross contamination in next product.	Remains of the previous product may contaminate the next product	Procedure for cleaning of the dry syrup filling machine is in place. Line clearance activity is done before start of the each batch. Swab samples are analyzed for the remains of previous batch after Type "B" cleaning.	SOP	3	3	3	27	Medium Risk category 1. SOP Operation and Cleaning of Dry Powder Filling Machine shall be revised to include the pictorial display for the parts need to be cleaned. 2. SOP Cleaning of Room During Product Changeover shall be revised to elaborate the cleaning	3	2	2	12
		Cleaning procedure of the area	Contamination/ cross contamination in next product. Failure of area during environmental testing	Remains of the previous product may contaminate the next product. Further chances to increase in microbial load	Procedure for cleaning of the process area is in place. Line clearance activity is done before start of the each batch. Procedure for prevention of contamination and cross contamination is in place. Environmental monitoring is carried out of the area at predefined frequency.	SOP	3	3	3	27		3	2	2	12



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												S	O	D	RPN SxOxD
											<p>procedure.</p> <p>3. The QC analysis data for five previous batches shall be reviewed for absence of any unwanted peak during analysis to mitigate the chances of cross contamination</p> <p>4. The MLT testing shall be performed on the previous batch.</p>				



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Remarks (if any):- Cleaning of dry syrup filling machine and the area leads to medium risk, which can be lower down after revision of the standard operating procedure of the dry syrup filling machine and the procedure for cleaning of room. The training on the revised procedure shall be imparted to concerned person.

S. No.	Recommended Action	Responsible Person	Target Date of Completion
1.	SOP Operation and Cleaning of Dry Powder Filling Machine shall be revised to include the pictorial display for the parts need to be cleaned.		
2.	SOP Cleaning of Room During Product Changeover shall be revised to elaborate the cleaning procedure.		
3.	The QC analysis data for five previous batches shall be reviewed for absence of any unwanted peak during analysis to mitigate the chances of cross contamination.		
4.	The MLT testing shall be performed on the previous batch. Product		

CAPA (Required / Not Required):
If required, mention CAPA No.: NA

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

QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

Name of Activity: Dry syrup filling machine and area



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Verification of Recommended Action:

Remarks (if any):

Verified By
Officer/Executive QA
(Sign & Date)

Approved By
Head QA
(Sign & Date)