



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## RISK ANALYSIS STUDY FOR DRY SYRUP BOTTLE CLEANING MACHINE

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.	Operation time entry was not recorded in the machine utilization record of bottle washing machine found it in ....., Product .	Cleaning activity of the bottles for dry syrup for the said batch may not be performed.	Contamination in next product.	The foreign particles / microbial contamination may carry forward in the product.	Procedure for cleaning of the dry syrup bottles is in place.	SOP no.	3	3	3	27	Medium Risk category  1. GDP training shall be imparted to all concerned person.  2. The MLT testing shall be performed on Product.	3	2	2	12

**Remarks (if any):-** Missing of the cleaning of dry syrup bottles leads to medium risk, which can be lower down if recording of the activity done in the log book. The training is being imparted to concerned person.



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S. No.	Recommended Action	Responsible Person	Target Date of Completion
1.	GDP training shall be imparted to all concerned person.		
2.	The MLT testing shall be performed on 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		



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**QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT**

**Name of Procedure: Dry syrup bottle cleaning machine**

**Verification of Recommended Action:**

**Remarks (if any):**

**Verified By  
Officer/Executive QA  
(Sign & Date)**

**Approved By  
Head QA  
(Sign & Date)**