



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ANALYSIS STUDY FOR RLAF CLEANING PROCEDURE

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.	Cleaning of dispensing booth filters to be revised from every change over to weekly or whenever D.P. limit exceeds its limit	RLAF Failure	Pressure differential will get disturbed	Leading to increase in Non viable count	Pressure differential is monitored while giving line clearance before each Dispensing.	SOP no.	3	3	3	27	Medium Risk category	3	1	4	12
		HEPA filters integrity	Filters may get choked	Due to dust collection	Differential pressure is measured/recorded to monitor the filter integrity as per sop	SOP no.	4	2	3	24	Low Risk category	4	1	3	12
		Environmental monitoring.	<ul style="list-style-type: none"> • Non Viable particle count will increase. • Viable particle count will increase 	This leads to cross contamination	<ul style="list-style-type: none"> ➤ Type-A cleaning procedure. • Clean the Area using under RLAF will be cleaned with vacuum Cleaner or clean cloth and the same area will be sanitized with 70% IPA solution. ➤ Type-B cleaning procedure. • After completion of Sampling or Dispensing, Air Blower will be switched "OFF" after 05 minutes from completion of sampling or dispensing activity and Washing the area. ▪ Sampling / Dispensing 	SOP no.	4	3	3	36	Medium Risk category	3	2	3	18



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												S	O	D	RPN SxOxD
					<ul style="list-style-type: none"> ▪ Wipe the Sampling and dispensing tools with dry lint free cloth and check the Sampling and dispensing tools visually clean for any adhesive particles and kept in double polythene bag with cleaned status label. ▪ Differential pressure verification. 										
		Air flow pattern change	Pre filter may get choked	If filter not cleaned properly, after every dispensing activity, filter may get choked	<p>After each dispensing activity, pressure differential is monitored & filter to be cleaned as per given procedure.</p> <p>Differential pressure in placed to monitor the pressure load checked before every line Clearance</p>	SOP no.	3	2	3	18	Low Risk category	3	1	4	12
2.	Return riser cleaning the filter on weekly	Filters may get choked	Area may get contaminated.	Dispensed material may be contaminated.	<ul style="list-style-type: none"> ➤ Type-A cleaning procedure. ● Clean the Area using 	SOP no.	4	3	3	36	Medium Risk category	3	2	3	18



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												S	O	D	RPN SxOxD
					& and kept in double polythene bag with cleaned status label.	SOP no.									

Remarks (if any):- Cleaning of dispensing booth filters leads to medium risk, which can be lower down after regular monitoring of pressure differential and verification of RLAF cleaning procedure.

S. No.	Recommended Action	Responsible Person	Target Date of Completion
1.	Regular monitoring of pressure differential to be done for 09 days or whenever D.P. limit exceeds its limit before increasing cleaning frequency.		
2.	RLAF cleaning procedure to be verified with approved protocol.		
3.	SOP Cleaning of Reverse Laminar Air Flow Filters and Grills to be revised.		

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

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:	Procedure
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Verification of Recommended Action:

Remarks (if any): Recommendation of regular monitoring of pressure differential to be done DP limit exceeds its limit before increasing cleaning frequency and RLAF cleaning procedure to be verified with approved protocol will be completed till the end of, Further SOP "Cleaning of RLAF and Grills" has been revised.

Verified By
Officer/Executive QA
(Sign & Date)

Approved By
Head QA
(Sign & Date)