PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR DISPENSING DPI

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

Name of Facility / Equipment / Utility / System / Activity / Procedure / Unit Operation for: Dispensing (DPI)	**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.	**Raw Material Dispensing**	Risk of Cross Contamination	Material & product contaminated.	Pressure differential not in limit.	Magnehelic gauges are provided in the facility. Checking & logging of differential pressure is done twice in a shift for critical areas. At the time of line clearance differential pressure verification is also done by QA.	**SOP**	4	1	4	16	NA	NA	NA	NA	NA
				Person carrying out the dispensing activity is not following proper gowning procedure.	Gowning procedure is available & pictorials are displayed in all changing room. Before authorize any person to entry in the critical areas training is carried out on entry procedure, gowning procedure & working procedure.	**SOP**	4	1	2	8	NA	NA	NA	NA	NA
				Person carrying out dispensing activity is suffering from infectious disease.	Person suffering from any infectious disease is not allowed to enter in the premises. Medical checkup of persons working in critical	**Training calendar**	4	1	2	8	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
	Raw Material Dispensing	Risk of Cross Contamination	Material & product contaminated.		areas is carried out on annual basis.										
				Due to damaged material container.	At the time of material receiving check point of container condition is available. At a defined frequency material condition is also verified as per procedure including container physical conditions.	**Check list of material receiving**	4	1	1	4	NA	NA	NA	NA	NA
				Due to improper cleaning of scoops & utensils used for dispensing.	Cleaning of all equipments& utensils is done by trained professionals by using validated cleaning procedures.	**SOP**	4	1	2	8	NA	NA	NA	NA	NA
				Due to improper cleaning of area.	As per procedure & GMP practices cleaning is done before the critical activity & verification of cleaning also done by QA person as per check point of line clearance.	**SOP**	4	1	4	16	NA	NA	NA	NA	NA
				Cleaning of the area is running simultaneously with dispensing.	As per procedure & GMP practices cleaning is done before the critical activity.	**SOP**	4	4	1	16	NA	NA	NA	NA	NA
				Due to improper cleaning of area.	Cleaning of area is done by validated & defined	**SOP**	4	1	2	8	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
	Raw Material Dispensing				cleaning procedure with the help of validated disinfectant.										
				RLAF operation is not done properly.	Operation & cleaning procedure of RLAF is done by defined procedure only by trained staff.	**SOP**	4	1	2	8	NA	NA	NA	NA	NA
				RLAF is not working properly.	Preventive maintenance of RLAF s done routinely. For checking performance of RLAF viable monitoring is done on daily basis.	**SOP**	4	1	1	4	NA	NA	NA	NA	NA
				AHU is not working properly.	Preventive maintenance of AHU's is done at defined frequency. For checking performance of AHU viable monitoring is done on weekly basis. Performance of dispensing area AHU is also checked on annual basis by performing air velocity, filter integrity, flow pattern, Recovery, leakage test. Temperature, RH & pressure differential is monitored twice in a day.	**SOP**	2	2	2	16	NA	NA	NA	NA	NA
				Person performing dispensing is not	Before dedicating any person for any activity	**SOP**	3	2	2	12	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
	Raw Material Dispensing			properly trained.	training related to the activity is given & after evaluating training authorization is given by QA Head to start working related to the activity on regular basis.										
				Use of un-cleaned gowns.	Washing and sterilization of gowns is done on daily basis. At exit change room bin for used garments (washable+ Disposal) is kept to put used garments. Washable garments from used bin are transferred to washing area whereas disposable gowns are disposed by housekeeping professionals.	**SOP**	4	1	2	8	NA	NA	NA	NA	NA
				Pass box used for material transfer from storage area to dispensing area is not working properly.	Preventive maintenance of pass box is done on quarterly basis.	**SOP**	4	2	2	16	NA	NA	NA	NA	NA
				Person is not performing sanitization of hands properly.	Training for entry & exit procedure is given to each individual intended for the area. Training evaluation is also done. Hand sanitization procedure with	**SOP**	4	1	3	1	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
					pictorial is also available in identified change rooms.										
	Raw Material Dispensing			Cleaning of area is not done properly.	Cleaning procedure is available Disinfectant used for cleaning of area are also validated. Persons dedicated for cleaning are also trained.	**SOP**	4	2	2	16	NA	NA	NA	NA	NA
				Improper cleaning of RLAF.	Cleaning procedure of dispensing booth is available & cleaning of booth is done on daily basis or after every dispensing by trained persons.	**SOP**	2	1	4	8	NA	NA	NA	NA	NA
				Improper cleaning of Pass Box.	Cleaning procedure of pass box is available & cleaning of pass box is done on daily basis by trained persons.	**SOP**	3	2	3	18	NA	NA	NA	NA	NA
				RLAF is not working properly.	RLAF working is checked by viable monitoring on daily basis. After every 06 moth qualification of RLAF is also checked. Preventive maintenance schedule of RLAF is also available. Magnehelic gauge pressure reading monitoring performs on daily basis.	**Qualification Protocol**	2	4	1	8	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
	Raw Material Dispensing			Untrained staff. Dispensing procedure not followed.	Before authorize to any person to carry out dispensing activity training is carried out related to the all activities at the time of dispensing. After training person is evaluated by QA head & after satisfactory observation he/she is authorized to carry out dispensing activity.	**SOP**	4	1	4	16	NA	NA	NA	NA	NA
				Washing area for utensils is not separate.	In the designed facility washing area is kept separately from the utensils washing area.	**Facility Layout**	3	2	3	18	NA	NA	NA	NA	NA
		Risk of Mix ups	Risk to patient & product safety & efficacy.	Wrong material may get dispensed.	Only trained person are authorized to carry out dispensing. Men & material movement is kept different. Proper labeling system is followed. At one time only one product dispensing is allowed to avoid mix ups	**SOP**	4	1	2	8	NA	NA	NA	NA	NA
			Risk to product & patient safety.	Wrong labeling	Proper labeling system is available & followed by trained persons.QA also checks labeling of the material.	**SOP**	4	1	4	16	NA	NA	NA	NA	NA
			Risk to	Wrong material	Proper labeling system is	**SOP**	4	1	3	12	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
	Raw Material Dispensing		product & patient safety.	dispensing	available & followed by trained persons.QA also checks labeling of the material.										
			Risk to product & patient safety.	Quantity of material wrongly taken.	Proper labeling system is available & followed by trained persons.QA also checks labeling of the material.	**SOP**	4	1	4	16	NA	NA	NA	NA	NA
		Risk to person Safety.	Loss of material & exposure of material directly with person.	Due to spillage of material	Spill kit, safety devices are available & persons are properly trained for its use.	**SOP**	3	1	3	9	NA	NA	NA	NA	NA
			Person Health & life.	Due to unavailability of safety devices.			4	1	3	12	NA	NA	NA	NA	NA
		Mixing of dispensed material.	Chances of mixing, contamination & cross contamination .	Due to presence of various material & product in the same area.	After dispensing dispensed material for single product is packed in a tightly closed container. Proper labeling system is followed & in staging area single batch material is stored on a single pellet with proper labeling. At the time of material receiving production person in presence of QA	**SOP**	4	1	3	12	NA	NA	NA	NA	NA

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	Raw Material Dispensing				verify the qty. of material against master formula & label pasted on the material. Verification of material qty. is done with the help of calibrated balance & balance calibration is done by production person familiar with the procedure. QA verify the calibration status of balance with the help of label pasted on it										

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:	**Raw Material Dispensing**

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