PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MANUFACTURING OF DPI

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

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.	**Disinfectant solution filtration**	Risk of contamination, improper filtration & sterility failure after filtration of Disinfectant solution	Sterility not gets achieved.	Filter size & material is not as per requirement.	Filtration of solution is performed under Grade A environment surrounded by Grade B in aseptic area. At the time of filter receiving filter is checked against COA to verify the pore size & also to check the bubble point pressure. As per procedure all persons undergo training procedure before authorize to perform activity. Only trained persons are authorized to perform critical operations. To perform sterile activity each person should also undergo personnel qualification procedure so that he must be trained & evaluated against aseptic procedures & behavior in sterile area. Before filtration & equipments is sterilized as per validated procedures & verification of sterilization	**Product BMR Training record of the personnel**	3	1	3	9	NA	NA	NA	NA	NA
			Filtration not done properly.	Filter integrity not checked.			4	1	3	12	NA	NA	NA	NA	NA
			Product loss	Connections not tighten properly.			4	1	4	16	NA	NA	NA	NA	NA

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	Disinfectant solution filtration				is done by QA. Before solution filtration filter integrity is checked by checking pre bubble point & after solution filtration by post bubble point. Filter used for solution filtration are single use sterilized membrane filter										
2.	**Washing & Sterilization of Containers.**	Risk of product contamination & patient safety.	Product may get contaminated & contamination may harm to patient health. Due to product contamination death & adverse reactions may also happens.	Sterilizer is not working properly.	Sterilizer working & performance is checked on six month frequency & also preventive maintenance has been performed on every 03 month basis.	**Respective Protocol**	4	1	4	16	NA	NA	NA	NA	NA

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	Washing & Sterilization of Containers.		Product may get contaminated & contamination may harm to patient health. Due to product contamination death & adverse reactions may also happens	Washing & sterilization is not done by trained operator.	Only trained & authorized persons are allowed to work in the designated area under the supervision of trained supervisor. QA also monitors that each activity should be performed by trained persons.	**SOP**	4	2	3	24	NA	NA	NA	NA	NA
				Equipment is not qualified.	Before starting activity qualification status of equipments also verified by QA.	**Respective Qualification Protocol**	4	3	1	12	NA	NA	NA	NA	NA
				Sterilization is not as per validated procedure.	Each & every activity shall be performed as per defined process in the batch records. Batch records are approved by QA considering all parameters & after that QA monitors that activity should be performed as per defined procedure.	**Respective BMR**	4	2	1	8	NA	NA	NA	NA	NA
3.	**Filling & Sealing**	Risk of Contamination, Cross Contamination & Sterility failure.	Risk for patient & product safety.	Operator not familiar with the aseptic area criticality.	After satisfactory evaluation of training related to aseptic area & personnel qualification observations person is	**Personal Training Record & Personal Qualification**	4	3	1	12	NA	NA	NA	NA	NA

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		Risk of Contamination, Cross Contamination & Sterility failure.			permitted to work in aseptic area. Trained operators are recruited to handle the machine & they also trained for the company equipments. Trained IPQA person remains in the aseptic area during entire process & monitors the operation along with production supervisor.										
	Filling & Sealing		Risk for patient & product safety.	Filling is done by untrained or unauthorized operator.	After satisfactory evaluation of training related to aseptic area & personnel qualification observations person is permitted to work in aseptic area. Trained operators are recruited to handle the machine & they also trained for the company equipments. Trained IPQA person remains in the aseptic area during entire process & monitors the operation along with	**Personal Qualification**	3	1	1	3	NA	NA	NA	NA	NA
			Risk for patient & product safety.	Defect in sealing & bugging.			4	2	2	16	NA	NA	NA	NA	NA
			Risk for patient & product safety.	Volume Variation.			3	1	4	12	NA	NA	NA	NA	NA

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							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
					production supervisor.										
			Risk for patient & product safety.	Risk for sterility maintenance.	Filling operation is carried out in aseptic area under Grade A environment. Machine parts &equipments are sterilized prior to operation. Hold time for sterilized equipments& accessories are validated. Transfer of sterilized articles & product is carried out under qualified mobile LAF. Sterility of the articles maintained properly. Operators are trained for handling of sterilized articles. All machine connections are done under grade A environment. Media fill also performed for checking sterility confidence in the process.	**Batch Manufacturing Record** **Qualification of Mobile LAF**	3	2	3	18	NA	NA	NA	NA	NA
4.	**Visual Inspection**	Inspection not done accurately.	Risk to product safety/ Person Safety	Inspectors are not qualified.	Qualification procedure of visual inspector is available & followed properly.	**Qualification Protocol**	2	1	4	8	NA	NA	NA	NA	NA
				Light intensity of booth	Procedure, frequency for	**Booth**	4	1	4	16	NA	NA	NA	NA	NA

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				is not proper for visual inspection.	checking of light intensity is available. Light intensity of booth is checked at defined frequency & recorded. In case of deviation from the defined limit replacement also done.	**Qualification**									
				Mixing of good & rejected containers.	Color coding of rejected & good vials container is kept different to avoid mix up of rejected & good containers.		4	1	4	16	NA	NA	NA	NA	NA
				Visual inspectors are not re-qualified at the defined frequency.	Medical checkup of visual inspectors are done on semiannual basis.	**Medical Report**	4	3	2	24	NA	NA	NA	NA	NA
				Inspection booth is not qualified	Before giving line clearance QA person checks the qualification of visual inspectors. This check is available in line clearance checks of the QA.	**Line Clearance SOP**	4	3	2	24	NA	NA	NA	NA	NA
5.	**Secondary & Tertiary packing of Injectable**	Risk of Mixing Misbranding &miss- labeling.	Risk to patient safety product safety & efficacy.	Wrong labeling	At the time of dispensing of packing material stores labels the material properly this is verified by QA. At the time of material	**BPR & BPR**	4	1	4	16	NA	NA	NA	NA	NA

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	Secondary & Tertiary packing of Injectable				receiving production person also verifies the material. Before starting packing activity QA verifies the absence of any other product material in the packing area & also cleaning of the area. In the beginning of the coding of the packing material production person checks the coding detail which is verified by the QA. During packing activity in process checks is carried out by production & QA persons at the defined frequency. Sample after packing is also send to QC for identification test to avoid any misbranding or mismatching..On the other hand, semi finished product in the quarantine is stored with proper labels. At the time of activity start production & QA also verify the details									

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					mentioned on labels										
6.	**Transfer & storage of finished goods to finished product store.**	Breakage of glass containers.	Product safety will be on risk.	Commercial loss & loss of product.	Although transfer of finished goods from the injection facility to finished product storage area is done manually but this activity is performed by trained persons & under the supervision of trained supervisor.	**BMR & BPR**	4	1	4	16	NA	NA	NA	NA	NA
		Degradation of product due to unfavorable environment conditions.	Patient safety will be on risk,	Effect on efficacy & safety of product.	Dedicated storage area for finished product is available in which optimum environment conditions are monitored. Environment conditions of the area are monitored twice in a 8 hrs. Shift. Also temp. Mapping of the area is preformed on annual basis for 3 days.	**BMR & BPR**	4	2	4	32	NA	NA	NA	NA	NA
7.	**Dispatch of finished**	Breakage of glass containers.	Product safety will be on	Commercial loss & loss of product.	Transportation conditions are maintained during	**BMR & BPR**	4	1	3	12	NA	NA	NA	NA	NA

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	goods.		risk.		transportation. For glass containers 7 ply shippers is used to pack the product. Warning is pasted on shippers" Glass inside Handle with care".										
		Degradation of product during transportation due to unfavorable environment conditions.	Patient safety will be on risk,	Effect on efficacy & safety of product.			4	1	4	16	NA	NA	NA	NA	NA
8.	**Batch release**	In-complete analytical records and QA release documentation	System failure/ Market Complaint	➢No SOP for review of analytical records ➢No SOP for batch release	➢SOP for review of analytical records ➢SOP for review batch release	SOP	4	3	2	24	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:	**Manufacturing (DPI)**

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):

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_____

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Verified By
QA
Sign & Date

Approved By
Head QA
Sign & Date