PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSEMENT FOR STERILIZE MACHINE PARTS TRANSFER FROM MOBILE LAF TO FILLING LAF

QRA No.:

Name of Facility/Equipment/Utility/System/Activity/Procedure **Unit Operation**: Sterilize Machine parts transfer from Mobile LAF to Filling LAF	**Date of Quality Risk Assessment:**

S.No.	Item/ Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure (Effect)	Potential Cause/ Mechanism of Failure	Current Control	Reference	S	O	D	Risk Priority Number (S*O*D)	Recommend-ended Actions (if any)	Post Risk			
												S	O	D	RPN S*O*D
1.	Machine parts & Filling Assembly	➢ Aseptically not Transfer from Mobile LAF to under Filling LAF.	Product contamination	➢ There is no procedure for transferring sterilized components from Grade A to A Area. ➢ During unloading of the sterilized components from mobile LAF trolley to under B grade area near to filling machine ➢ Not Uniform unidirectional flow during machine parts transfer from Mobile LAF to Filling LAF. ➢ Turbulent or insufficient flow may lead to particulate contamination of the product inside Vials.	➢ Machine parts carry in Mobile LAF and assembled under LAF, Which is operated through battery backup. ➢ Environment qualification Air flow test demonstrating at operation laminarity has been maintained ➢ Machine parts wrapped with double bio barrier paper and bio barrier paper open in under LAF . ➢ Air velocity has been carried out during qualification for verification of the same. ➢ Smoke study has been performed during machine parts transfer from mobile LAF to filling LAF and during machine parts assembling for verification of the same. ➢ Surrounding area and under LAF area is closely monitored by viable and non-viable particle count include personal monitoring.	As Per SOP & Validation record	4	2	1	8 Low category & Risk Accepted	Smoke study to be performed to verify the air visualization.	NA	NA	NA	NA

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2.	Machine parts & Filling Assembly	➢ Aseptically not Transfer from Mobile LAF to under Filling LAF.	Product contamination	➢ There is no online particle count system to capture particulate matter during filling.	➢ Line clearance given based on NVPC and after installation of machine parts again taken 36 minute NVPC data for DPI line and continue monitoring in Ampoule, vials and ophthalmic solution. ➢ Machine parts transfer procedure including loading-unloading of sterile component has been simulated during process simulation study (media fill) ➢ Smoke study has been conducted to demonstrate that during operation laminarity is not affected over the work zone. ➢ Surrounding area and under LAF area is closely monitored by viable and non-viable particle count include personal monitoring. ➢ A personnel involved in filling operation has been qualified to enter in aseptic area.	As per Batch manufacturing record & Media fill record.	4	1	1	4 Low category & Risk Accepted	Adequate procedure no recommendation required.	NA	NA	NA	NA

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3.	Machine parts & Filling Assembly	➢ Cleaning not properly done	➢ Directly impacted to product	➢ Written procedure for machine parts cleaning not available ➢ After cleaning verification process not available	➢ Cleaning of machine parts is done as per the respective SOP. ➢ After cleaning all details recorded in batch manufacturing record.	As per SOP & BMR	4	2	1	8 Low category & Risk Accepted	Adequate procedure no recommendation required.	NA	NA	NA	NA
4.	Machine parts & Filling Assembly	➢ Materials/ machine parts are not sterilized by utilizing the validated parameters.	➢ Machine parts not sterilized properly.	➢ Unqualified autoclave used for sterilization process ➢ Un-qualified load patterns used. ➢ Mechanical problem in autoclave. ➢ Working personnel lack of adequate knowledge. ➢ Impure steam provided by PSG.	➢ Autoclave qualification has been done and a validated load pattern is provided to production. ➢ Preventive maintenance is done as per schedule. ➢ Trained Person handles the all autoclave processes. ➢ PSG is qualified and produces a quality & pure steam for autoclaving process.	As per Qualification record	4	2	1	8 Low category & Risk Accepted	Adequate procedure no recommendation required.	NA	NA	NA	NA
5.	Machine parts & Filling Assembly	➢ Aseptically not handling after sterilization.	Product contamination	➢ Carry and kept without laminar air ➢ Use over the recommendation periods ➢ Machine parts in open condition.	➢ Machine parts carry in Mobile LAF and assembled under LAF, Which is operated through battery backup. ➢ Hold time given in BMR and training has been providing to all concerned person. ➢ Machine parts wrapped with double bio barrier paper and bio barrier paper open in under LAF.	As per SOP	3	2	1	6 Low category & Risk Accepted	Adequate procedure no recommendation required.	NA	NA	NA	NA

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6.	ORABs access doors	➢ ORABs access door may be opened during process.	➢ Chances of product contamination by direct handling of operators.	➢ There is no provision for access the door with the interlocking system. ➢ There is no alarm provision provided.	➢ Security switches/ sensors are provided at the access doors with interlock feature with the operation of machine i.e. machine stops immediately if ORABs access doors are opened. ➢ Alarm provision has been also provided for the same.	As Per SOP & Validation record	3	1	1	3 Low category & Risk Accepted	Adequate procedure no recommendation required.	NA	NA	NA	NA
7.	Mobile trolley	➢ Common mobile trolley is used for transferring the material like machine parts etc.	➢ Cross contamination occurs between the adjacent areas.	➢ Single trolley is available and in uses for transferring the material to both areas.	➢ There are Dedicate mobile trolley used for transferring the material.	As Per SOP	2	2	1	4 Low category & Risk Accepted	Adequate procedure no recommendation required.	NA	NA	NA	NA
8.	LAF (Over Filling & discharge conveyor)	➢ The air flow from LAF is not uniform or is turbulent.	➢ Turbulent or insufficient flow may lead to particulate contamination of the product inside Vials.	➢ Uniform unidirectional flow not maintained from the LAF. ➢ Air velocity is not maintained at the working level. ➢ Air velocity and filter integrity didn't carry out during qualification.	➢ Uniform unidirectional flow maintained from the LAF up to the working area inside oRABs. ➢ A uniform air velocity of 90 fpm ± 20% has been maintained at the working level inside oRABs. ➢ Air velocity and smoke study has been carried out during qualification for verification of the same.	As Per Qualification Record	3	2	1	6 Low category & Risk Accepted	Adequate procedure no recommendation required.	NA	NA	NA	NA

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9.	LAF (over Filling & discharge conveyor)	➢ LAF fails / Stops	➢ Contamination of product is possible if machine is in operation.	➢ No interlocking system is available with LAF Operation. ➢ Machine running continuously in case of any LAF failure. ➢ UPS backup not available for LAF. ➢ There is no alarm provision if in case LAF fails/Stops.	➢ Machine operation is interlocked with LAF's operation, which are mounted on top of the entire filling & Stoppering machine and on its infeed and discharge side. ➢ Machine stops in case of any LAF failure. ➢ LAF connect with UPS backup to avoid any failure. ➢ Alarm provision has been provided in case of LAF fails/ stops.	As Per Qualification Record	3	2	1	6 Low category & Risk Accepted	Adequate procedure no recommendation required.	NA	NA	NA	NA
10.	Filling & sealing process	➢ Failure of LAF during the filling operation.	➢ Filling during switch off condition of LAF will directly impact the sterility of the sterility of the product.	➢ There might be failure of sensor & Problem in input-output command by PLC. ➢ Non-qualified Laminar air flow unit used for filling operation. ➢ No preventive maintenance of LAF.	➢ During operational qualification all sensors has been verified. ➢ Performance requalification of LAF has been completed. ➢ Preventive maintenance of LAF done as per schedule.	As Per SOP & Qualification record	4	2	1	8 Low category & Risk Accepted	Adequate procedure no recommendation required.	NA	NA	NA	NA

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11.	Filling & sealing process	➢ During filling power failure of LAF.	➢ Filling during power failure condition of LAF will directly impact the sterility of the sterility of the product and there might be a chance of contamination of product.	➢ Failure of power supply in aseptic area. ➢ Failure of UPS Backup of filling LAF.	➢ During power failure of LAF all filling operation will stop. ➢ A proper training has been provided to concerned personnel that filling operations shall be done only under LAF and also background of LAF shall be maintained as per specific grade requirement.	As per SOP	2	2	1	4 Low category & Risk Accepted	Adequate procedure no recommendation required.	NA	NA	NA	NA

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12.	Filling & stoppering	➢ Filling & stoppering carried out under unclean environment	➢ Particle contamination of product. ➢ Micro-biological contamination possible.	➢ Grade A and unidirectional airflow is not available for performing aseptic filling & stoppering process. ➢ Online NVPC not available ➢ Environmental monitoring and Personal monitoring procedure not available.	➢ Unidirectional Air Flow system (Grade A) is provided over complete filling & stoppering machine. ➢ Classification level has been verified and qualified during the qualification study. ➢ Surrounding area and under LAF area is closely monitored by viable and non-viable particle count include personal monitoring. ➢ Line clearance given based on NVPC and after installation of machine parts again taken 36 minute NVPC data and continue monitoring in Ampoule ,vials and ophthalmic solution	As Per SOP & Viable & Non-Viable data	4	2	1	8 Low category & Risk Accepted	Adequate procedure no recommendation required.	NA	NA	NA	NA
13.	Area monitoring by settle plate & active air sampling	➢ Irregular monitoring intervals. ➢ Inadequate detailing of test locations (sample points)	➢ Area monitoring effected and can not record as per the time schedule. ➢ Critical locations can be left without monitoring.	➢ No schedule of area monitoring ➢ No justified and approved locations for area sampling. ➢ Working personnel lack of adequate knowledge.	➢ The area monitoring has been done as per the schedule for the different area. ➢ There are proper approved sampling locations for area monitoring. ➢ Trained personnel done the area monitoring.	As Per SOP	3	1	1	3 Low category & Risk Accepted	Adequate procedure no recommendation required.	NA	NA	NA	NA

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14.	Area Cleaning	Area cleaning not done after batch completion.	There is a high degree of chances to increase the chemical & microbial growth in the area that can lead product contamination also.	Unawareness of operator and staff members. Working personnel lack of adequate knowledge.	Only trained and authorized per can enter & work in the aseptic area and they all are trained in their work. After completion of every batch the cleaning has been done in the presence of production and quality assurance personnel.	As Per SOP	4	1	1	4 Low category & Risk Accepted	Adequate procedure no recommendation required.	NA	NA	NA	NA
15.	Area Cleaning	Area cleaning not done as per the schedule.	High chances to increase the microbial growth in the area that can lead product contamination also.	No schedule is there for area cleaning. SOP of area cleaning not followed. Working personnel lack of adequate knowledge.	There is a proper schedule for cleaning of aseptic area and cleaning has been done as per the schedule by the trained personnel. SOP of area cleaning has been followed and log in the all details in respective log book.	As Per SOP	4	2	1	8 Low category & Risk Accepted	Adequate procedure no recommendation required.	NA	NA	NA	NA
16.	Area Cleaning	Microbial growth increases in aseptic area.	Product get contaminated Product failure.	Disinfectant using area cleaning not validated. Effectiveness of disinfectant not up to the mark.	Disinfectant validation has been done and only validated disinfectant has been used for cleaning of aseptic area.	As Per SOP	2	2	1	4 Low category & Risk Accepted	Adequate procedure no recommendation required.	NA	NA	NA	NA
17.	Garment sterilization	➢ Garments are not sterilized by utilizing the validated parameters.	➢ Garments for aseptic area not sterilized properly.	➢ Unqualified autoclave used for sterilization process ➢ Un-qualified load patterns used. ➢ Mechanical problem in autoclave. ➢ Working personnel lack of adequate knowledge.	➢ Autoclave qualification has been done and a validated load pattern is provided to production. ➢ Preventive maintenance is done as per schedule. ➢ Trained Person handles the all autoclave processes.	As Per SOP & Qualification Record	3	3	1	9 Low category & Risk Accepted	Adequate procedure no recommendation required.	NA	NA	NA	NA

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18.	Sterile Garment storage	➢ Garments stored in unclassified & unqualified place. ➢ Garments hold up in same place for more than specified time duration.	➢ Sterilized garments can get contaminated by exposing and stored for more than specified time duration in outer area. ➢ Contaminated garment can also contaminate the aseptic area. ➢ Product can get easily contaminated by garments.	➢ No specific place provided for storing the sterile garments. ➢ Garments hold time duration not specified. ➢ Working personnel lack of adequate knowledge.	➢ Sterile garment storage cabinet is used for storing the sterile garments. ➢ Garment hold time study is established and a specified hold time period is recommended in respective SOP. ➢ Training provided to persons.	As per SOP	3	2	1	6 Low category & Risk Accepted	Adequate procedure no recommendation required.	NA	NA	NA	NA
19.	Man & material entry in aseptic area	Man & material entry not specified	There are high chances of cross contamination. It can cause product failure.	Man & material entry not properly segregated for entering in aseptic area. Entry & exit procedure for aseptic area not specified.	There are separate entry procedures for man & material. All materials for aseptic area has been transferred through Dynamic pass box, and all personnel have been enter in the aseptic area through 03 change room system as per the entry & exit procedure for aseptic area.	As Per SOP & Layout	4	1	1	4 Low category & Risk Accepted	Adequate procedure no recommendation required.	NA	NA	NA	NA
20.	Filling & sealing process	➢ Filling room differential pressure is out of range during product filling.	➢ Due to low DP there might be a risk of area contamination with respect to adjacent room followed by contamination in product.	➢ Due to insufficiency of AHU Performance. ➢ Non-qualified AHU used for operation.	➢ Audio visual alarm system is provided in BMS System when pressure differential will go out of limit. ➢ At the time of PQ pressure differential has been verified.	As per SOP & Qualification record	4	2	1	8 Low category & Risk Accepted	Adequate procedure no recommendation required.	NA	NA	NA	NA

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21.	Filling & sealing process	➢ Filling room temperature & RH is out of range during product filling.	➢ There might be an impact on in-process product.	➢ Due to inefficiency of chiller & heater of that particular AHU.	➢ Audio visual alarm system is provided in BMS System when temperature & RH will go out of limit. ➢ At the time of PQ temperature & RH has been verified.	As per SOP & Qualification record	3	1	1	3 Low category & Risk Accepted	Adequate procedure no recommendation required.	NA	NA	NA	NA

Where: S=Severity; O=Occurrence Probability; D=Detection; Risk category 1-25RPN is Low risk, 26-50 RPN is Medium Risk, 51-125 RPN is High Risk.

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Name of Facility/Equipment/Utility/System/Activity/Procedure/Unit Operation: Sterilize Machine Parts Transfer From Mobile LAF to Filling LAF	Date:

S. No.	Recommended Action	Responsible Person	Target Date of Completion
1.	NA	NA	NA
2.	NA	NA	NA

CAPA: 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 Equipment: Machine parts transfer from Mobile LAF to Filling LAF

Verification of Action Plan: NA

Remarks (if any): The entire above failure mode and their Severity, Occurrence, Detection rating done and RPN No. is found between 03 to 09. Hence Risk is detected as low which is acceptable.

Verified By
QA
Sign & Date

Approved By
Head QA
Sign & Date