QUALITY RISK ASSESSEMENT AND MITIGATION PLAN

QRA No.:

Name of Facility/Equipment/Utility/System/Activity/Procedure **Unit Operation**: Entry & Exit with Common Change Rooms	**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
Entry & Exit With Common Change Rooms:															
1.	HVAC System	➢ Air of three piece line got contaminated with dry powder line air.	➢ There are high chances of cross contamination. ➢ It can cause product failure. ➢ Product & Area got contaminated.	➢ Dedicated & Separate Air circulation system not provided.	➢ Separate & dedicated AHU are there for preventing the cross contamination in both areas (DPI & Three piece line) ➢ Due to dedicated AHU for both areas there is no chance of cross contamination in both areas through circulated air. ➢ A separate aseptic air lock is provided before entering in the dry powder injection filling room, which is basically in the form of bubble air lock, which prevents the cross contamination between dry powder filling room, aseptic corridor and three piece filling room.	As Per SOP & Validation record	3	1	1	3 Low category & Risk Accepted	Adequate procedure no recommendation required.				

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN

QRA No.:

Name of Facility/Equipment/Utility/System/Activity/Procedure **Unit Operation**: Entry & Exit with Common Change Rooms	**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
2.	Differential Pressure	➢ Differential Pressure decreases from its set parameters or acceptance limit.	➢ Cross contamination occurs between the adjacent areas.	➢ Low amount of air circulation in area. ➢ Differential pressure failure and goes out of limit. ➢ Desired ACPH not getting in area. ➢ Dumper can be not properly opened. ➢ Motor & blower do not working properly.	➢ Differential pressure is regularly monitored and controlled through BMS System. ➢ If the differential pressure goes out of limit then BMS system controls the differential pressure. ➢ Negative Pressure has been set in dry powder filling room due to that adjacent area not contaminated and dedicated separate aseptic air lock control the dry powder line air through bubble air lock system.	As Per SOP & Validation record	3	3	1	9 Low category & Risk Accepted	Adequate procedure no recommendation required.				
3.	Dust Collector of filling machine (DPI)	➢ Dust collector not working properly.	➢ Surrounding area of filling gets contaminated with powder.	➢ No proper connection has been done between suction pipe and duct collector. ➢ Suction pipe has been damaged ➢ Vacuum pump not working.	➢ Trained & Qualified person operate the dust collector. ➢ Before starting the filling operation it is mandatory to check all connections of dust collector. ➢ Preventive maintenance has been done as per schedule.	As Per SOP	3	3	1	9 Low category & Risk Accepted	Adequate procedure no recommendation required.				
4.	Mobile trolley	➢ Common mobile trolley is used for transferring the material like machine pasts etc.	➢ Cross contamination occurs between the adjacent areas.	➢ Single trolley is available and in uses for transferring the material to both areas.	➢ Separate and dedicated mobile trolley available for both areas.	As Per SOP & Validation record	4	1	1	20 High risk & adequate recommender action must be required.	➢				

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN

QRA No.:

Name of Facility/Equipment/Utility/System/Activity/Procedure **Unit Operation**: Entry & Exit with Common Change Rooms	**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
5.	Process	➢ Bulk solution of eye/ear drop spillage in the area.	➢ Cross contamination occurs	➢ Tank and transfer line not connected properly. ➢ Manual transfer line is available for transfer the solution.	➢ Integrated product line between manufacturing areas to filtration area to filling area is available for transfer the solution through pneumatic valve which is controlled by PLC.	As Per SOP & Validation record	4	2	1	8 Low category & Risk Accepted	Adequate procedure no recommendation required.				
6.	Area monitoring by settle plate & active air sampling	➢ Irregular monitoring intervals. ➢ Inadequate detailing of test locations (sample points)	➢ Area monitoring effected and cannot 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	2	1	6 Low category & Risk Accepted	Adequate procedure no recommendation required.				
7.	Cleaning & Sanitization	➢ 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.				

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN

QRA No.:

Name of Facility/Equipment/Utility/System/Activity/Procedure **Unit Operation**: Entry & Exit with Common Change Rooms	**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
8.	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 & Validation record	4	2	1	8 Low category & Risk Accepted	Adequate procedure no recommendation required.				

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN

QRA No.:

Name of Facility/Equipment/Utility/System/Activity/Procedure **Unit Operation**: Entry & Exit with Common Change Rooms	**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
9.	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. ➢ For cleaning and sanitization only validated & approved disinfectant in use and all validated disinfectants rotated as per scheduled frequency on daily basis. ➢ For avoiding the cross contamination in both filling room (DPI & Three Piece) have been cleaned with a separate lint free MOP and fresh solution. ➢ Both areas clean sequently and never cleaned both areas at a time. ➢ 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.				

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN

QRA No.:

Name of Facility/Equipment/Utility/System/Activity/Procedure **Unit Operation**: Entry & Exit with Common Change Rooms	**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
10.	Material entry in aseptic area	➢ Material entry not specified	➢ There are high chances of cross contamination. ➢ It can cause product failure.	➢ Material entry not properly segregated for entering in aseptic area.	➢ There are separate entry procedures for material. ➢ For dry powder and three piece line separate Dynamic pass boxes are available for material entry and there is no chance of cross contamination due to material entry in aseptic area. ➢ All materials for aseptic area has been transferred through Dynamic pass box. ➢ Separate sterile dispensing and sampling area is available for dry powder injection line.	As Per SOP & Validation record	3	1	1	3 Low category & Risk Accepted	Adequate procedure no recommendation required.				

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN

QRA No.:

Name of Facility/Equipment/Utility/System/Activity/Procedure **Unit Operation**: Entry & Exit with Common Change Rooms	**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
11.	Man entry in aseptic area	➢ Man entry not specified	➢ There are high chances of cross contamination. ➢ It can cause product failure.	➢ Man entry not properly segregated for entering in aseptic area. ➢ Entry & exit procedure for aseptic area not specified.	➢ There are two filling room with common entry and exit and a common corridor. So, for preventing the cross contamination dedicated Personnel have been provided for Both dry powder and three piece line. ➢ 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 & Validation record	4	2	1	8 Low category & Risk Accepted	Adequate procedure no recommendation required.				
12.	Man entry in aseptic area	➢ Gowning procedure not defined for entering in aseptic area.	➢ Sterile garments can be reused for second time for aseptic area.	➢ No proper training provided for gowning procedure. ➢ The procedure is not adequate as per aseptic behavior.	➢ An approved gowning procedure is followed and available in place. ➢ As per current written procedure reuse of sterile garments is not allowed for entry in aseptic area.	As Per SOP & Validation record	3	2	1	6 Low category & Risk Accepted	Adequate procedure no recommendation required.				

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.

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN

QRA No.:

Name of Facility/Equipment/Utility/System/Activity/Procedure **Unit Operation**: Entry & Exit with Common Change Rooms	**Date of Quality Risk Assessment:**

Name of Facility/Equipment/Utility/System/Activity/Procedure/Unit Operation: Purified water generation &distribution system	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**		

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN

QRA No.:

Name of Facility/Equipment/Utility/System/Activity/Procedure **Unit Operation**: Entry & Exit with Common Change Rooms	**Date of Quality Risk Assessment:**

QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

Name of Equipment: Entry & Exit with Common Change Rooms

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