PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ANALYSIS FOR AIR HANDLING UNIT

S. No.	Item / Function	Potential Failure Mode	Potential Effect of Failure	Potential Cause / Mechanism of Failure	Current Control	Reference Document no.	S	O	D	Risk Priority Number (S*O*D)	Recommended Actions (if any)	Post Risk			
												S	O	D	RPN S*O*D
1.	Size/Dimension of Machine/ Components may differ from specification	May lead to unavailability of space or Machine may not be installed into the area	Productivity may be effected due to space constrant	• Person Negligency • Unavailablity of qualification documents • Involvement of Untrained persons/Vendor in qualification • Procedure was not much established for qualification	• Performane Qualification has been performed • Standard Operating Procedure is in Place • Equipment is already been installed • Equipment/Machine is in operation for production	…….	**3**	**2**	**2**	**12**	Installation Qualification shall be performed and size/dimension shall verified in IQ	**3**	**1**	**1**	**3**
2.	Functionality of machine may differ from specification	Machine may be Malfunction	Dust may not be extracted from the workplace.	• Person Negligency • Unavailablity of qualification documents • Involvement of Untrained persons/Vendor in qualification • Procedure was not much established for qualification	• Performane Qualification has been performed • Standard Operating Procedure is in Place • Equipment/Machine is in operation for production • Equipment covered in Preventive Maintenance Program	…….	**4**	**3**	**3**	**36**	Operational Qualification shall be performed and functionality shall be verified	**4**	**1**	**1**	**4**
3.	Unavailability of vendor documents like operation and maintenance manual, functional specification and design specification may happen	It may lead to Lack of information of the Machine	During preparation of In-House Qualification documents, it may not cover all required test/Script	• Person Negligency • Unavailablity of qualification documents • Involvement of Untrained persons/Vendor in qualification • Procedure was not much established for qualification	• Performane Qualification has been performed • Standard Operating Procedure is in Place • Equipment/Machine is in operation for production	……..	**4**	**3**	**3**	**36**	All related In-house documents shall be prepared and shall be exeuted	**4**	**1**	**1**	**4**

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												S	O	D	RPN S*O*D
4.	Unavailability of GA drawing, Electrical drawings, components certificates and MOC certificates may happen	Arrangement of components and electrical wiring may not be identified	During any maintenance/Break down activity, Engineer may face problems related to components and wiring arrangement	• Person Negligency • Unavailablity of qualification documents • Involvement of Untrained persons/Vendor in qualification • Procedure was not much established for qualification	• Performane Qualification has been performed • Standard Operating Procedure is in Place • Equipment/Machine is in operation for production	……	3	3	3	27	Availablity for drawing to be check by Engineering/Vendor	3	1	1	3
5.	Safety parameters like noise level, surface finish and limit switch may not be available	Machine may not have safety features	May lead to effect on Operator/Personnel safety	• Person Negligency • Unavailablity of qualification documents • Involvement of Untrained persons/Vendor in qualification • Procedure was not much established for qualification	• Performane Qualification has been performed • Standard Operating Procedure is in Place • Equipment/Machine is in operation for production	…….	4	3	2	24	If equipment is sound producing in that case noise lavel shall be verified in OQ and surface finish and limit switch shall be verified in IQ	4	1	1	4
6.	Utility requirements for the machine may differ from specification	May lead to abnormal behavior of the Machine	Electrical/Mechanical Fault in the Machine may be happen	• Person Negligency • Unavailablity of qualification documents • Involvement of Untrained persons/Vendor in qualification • Procedure was not much established for qualification	• Performane Qualification has been performed • Standard Operating Procedure is in Place • Equipment/Machine is in operation for production	…….	4	1	3	12	Equipment was using since many years still utility shall be verified in IQ	4	1	1	4

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												S	O	D	RPN S*O*D
7.	Equipment may not be included in the Equipment master list, Preventive Maintenance Planner and Calibration Planner	Machine may not be scheduled for preventive maintenance and calibration	Dust may not be extracted from the workplace.	• Person Negligency • Unavailablity of qualification documents • Involvement of Untrained persons/Vendor in qualification • Procedure was not much established for qualification	• Performane Qualification has been performed • Standard Operating Procedure is in Place • Equipment/Machine is in operation for production	…….	**5**	**4**	**4**	**80**	Master list of equipment, Calibration planner, PM Planner shall be verified in IQ for equipment presense	**5**	**1**	**1**	**5**
8.	Machine Functions keys may not be work or work different	May lead to abnormal behavior of the Machine and may results in effects on Product/Human safety	Electrical/Mechanical Fault in the Machine may be happen	• Person Negligency • Unavailablity of qualification documents • Involvement of Untrained persons/Vendor in qualification • Procedure was not much established for qualification	• Performane Qualification has been performed • Standard Operating Procedure is in Place • Equipment/Machine is in operation for production	…….	**4**	**2**	**3**	**24**	Operational Qualification shall be performed and functionality shall be verified in OQ	**4**	**1**	**1**	**4**
9.	SOP may not be available or may not drafted accordingly	Operation and Cleaning of machine may effected	Dust may not be extracted from the workplace.	• Person Negligency • Unavailablity of qualification documents • Involvement of Untrained persons/Vendor in qualification • Procedure was not much established for qualification	• Performane Qualification has been performed • Standard Operating Procedure is in Place • Equipment/Machine is in operation for production	…….	**4**	**1**	**1**	**4**	NA	NA	N A	N A	NA

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												S	O	D	RPN S*O*D
10.	Safety interlocks may not work (Door or emergency)	Machine may not follow safety requirements	May lead to effect on Operator/ Personnel safety	• Person Negligency • Unavailablity of qualification documents • Involvement of Untrained persons/Vendor in qualification • Procedure was not much established for qualification	• Performane Qualification has been performed • Standard Operating Procedure is in Place • Equipment/Machine is in operation for production	……	**4**	**3**	**2**	**24**	Safety interlocks shall be verified in OQ (If Applicable)	**4**	**1**	**1**	**4**

S.No.	Recommended Action	Responsible Person	Target Date of Completion
1.	All identified qualification documents which are not available or not executed, shall be prepared and executed.		
2.	Further New equipments shall be qualified as per current SOP checklist.		
3.	GA/Electrical Drawing shall be prepared/arranged		
4.	Training shall be imparted to all concerned persons to ensure the adequacy, accuracy, completeness and correctness of the documents.		
5.	URS and SOP for the equipment shall be preparaed/Updated		

CAPA (Required/Not required): Not required
If required mentioned the CAPA No.: NA

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RISK ANALYSIS FOR AIR HANDLING UNIT

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 SUMMARY REPORT

Name of facility/Equipement/Utility/System/Activity/Procedure/Unit Preparation:	Risk assessment for gaps identified in Qualification Documents as per Change Control No……. Position Paper No…….

Verification of recommended action:

Remark (if any):

For Product Contact Equipments: All the product contact Machine/Equipment, which are covered in this risk assessment are procured from the vendor as on such basis and were used for routine production after performance qualification, hence there is no significant impact on product quality due to identified GAP's in Qualification Documents.

Process Validation: All identified equipments in this quality risk assessment are also covered in many process validation batches of OSD area. On behalf of our process validation study, it can be concluded that there is no significant impact on product quality due to identified GAP's in Qualification Documents.

Verified By:
Officer/Executive QA
(Sign & Date)

Approved By:
Head QA
(Sign & Date)