PHARMA DEVILS

RISK ASSESSMENT FOR PLANT EQUIPMENTS

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 • Equipments covered in PM 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	It may lead to Lack of information of the Machine	During preparation of In-House Qualification documents, it	• Person Negligency • Unavailablity of qualification documents	• Performane Qualification has been performed • Standard Operating		**4**	**3**	**3**	**36**	All related In-house documents shall be prepared and	**4**	**1**	**1**	**4**

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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	Recommended Actions (if any)	Post Risk			
												S	O	D	RPN S*O*D
	manual, functional specification and design specification may happen		may not cover all required test/Script	• Involvement of Untrained persons/Vendor in qualification • Procedure was not much established for qualification	Procedure is in Place • Equipment/ Machine is in operation for production						shall be exeuted				
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/Breakdown 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	• 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**

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												S	O	D	RPN S*O*D
				established for qualification											
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**
7.	Operating parameters (e.g. Min-max speed) may not be fixed or validated	Machine may be Malfunction	Standard Quality of tablet not meet as per requirement – may cause complaint.	• 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**	**2**	**4**	**40**	All Operating parameters shall be verified in OQ	**5**	**1**	**1**	**5**
8.	Machine Functions keys may not be	May lead to abnormal behavior of the	Electrical/ Mechanical Fault in the	• Person Negligency • Unavailablity of	• Performane Qualification has been performed		**4**	**2**	**3**	**24**	Operational Qualification shall be	**4**	**1**	**1**	**4**

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RISK ASSESSMENT FOR PLANT EQUIPMENTS

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	Recommended Actions (if any)	Post Risk			
												S	O	D	RPN S*O*D
	work or work different	Machine and may results in effects on Product/Human safety	Machine may be happen	qualification documents • Involvement of Untrained persons/Vendor in qualification • Procedure was not much established for qualification	• Standard Operating Procedure is in Place • Equipment/ Machine is in operation for production • Equipments covered in PM Program						performed and functionality shall be verified in OQ				
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	NA	NA	NA

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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	Recommended Actions (if any)	Post Risk			
												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**

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RISK ASSESSMENT FOR PLANT EQUIPMENTS

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	It may lead to Lack of information of the Machine	During preparation of In-House Qualification	• Person Negligency • Unavailablity of qualification	• Performane Qualification has been performed • Standard Operating	DER/017	**4**	**3**	**3**	**36**	All related In-house documents shall be prepared and shall be	**4**	**1**	**1**	**4**

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RISK ASSESSMENT FOR PLANT EQUIPMENTS

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	Recommended Actions (if any)	Post Risk			
												S	O	D	RPN S*O*D
	maintenance manual, functional specification and design specification may happen		documents, it may not cover all required test/Script	documents • Involvement of Untrained persons/Vendor in qualification • Procedure was not much established for qualification	Procedure is in Place • Equipment/Machine is in operation for production						exeuted				
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/Breakdown 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	• 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**

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RISK ASSESSMENT FOR PLANT EQUIPMENTS

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	Recommended Actions (if any)	Post Risk			
												S	O	D	RPN S*O*D
				not much established for qualification											
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**
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 lead to abnormal	Electrical/ Mechanical	• Person Negligency	• Performane Qualification has been		**4**	**2**	**3**	**24**	Operational Qualification shall	**4**	**1**	**1**	**4**

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RISK ASSESSMENT FOR PLANT EQUIPMENTS

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	Recommended Actions (if any)	Post Risk			
												S	O	D	RPN S*O*D
	may not be work or work different	behavior of the Machine and may results in effects on Product/Human safety	Fault in the Machine may be happen	• Unavailablity of qualification documents • Involvement of Untrained persons/Vendor in qualification • Procedure was not much established for qualification	performed • Standard Operating Procedure is in Place • Equipment/Machine is in operation for production						be performed and functionality shall be verified in OQ				
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	NA	NA	NA

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RISK ASSESSMENT FOR PLANT EQUIPMENTS

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	Recommended Actions (if any)	Post Risk			
												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**

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RISK ASSESSMENT FOR PLANT EQUIPMENTS

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		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	It may lead to Lack of information of the Machine	During preparation of In-House Qualification	• Person Negligency • Unavailablity of qualification	• Performane Qualification has been performed • Standard Operating		4	3	3	36	All related In-house documents shall be prepared and shall be	4	1	1	4

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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	Recommended Actions (if any)	Post Risk			
												S	O	D	RPN S*O*D
	maintenance manual, functional specification and design specification may happen		documents, it may not cover all required test/Script	documents • Involvement of Untrained persons/Vendor in qualification • Procedure was not much established for qualification	Procedure is in Place • Equipment/Machine is in operation for production						exeuted				
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/Breakdown 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	• 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**

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												S	O	D	RPN S*O*D
				not much established for qualification											
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**
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 lead to abnormal	Electrical/ Mechanical	• Person Negligency	• Performane Qualification has been		**4**	**2**	**3**	**24**	Operational Qualification shall	**4**	**1**	**1**	**4**

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RISK ASSESSMENT FOR PLANT EQUIPMENTS

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	Recommended Actions (if any)	Post Risk			
												S	O	D	RPN S*O*D
	may not be work or work different	behavior of the Machine and may results in effects on Product/Human safety	Fault in the Machine may be happen	• Unavailablity of qualification documents • Involvement of Untrained persons/Vendor in qualification • Procedure was not much established for qualification	performed • Standard Operating Procedure is in Place • Equipment/Machine is in operation for production						be performed and functionality shall be verified in OQ				
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	NA	NA	NA

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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	Recommended Actions (if any)	Post Risk			
												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**

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RISK ASSESSMENT FOR PLANT EQUIPMENTS

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 (Annexure-VIII of QAD/135)		
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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Quality Risk Management Team			Reviewed By Head Operations Sign & Date	Approved By Head QA Sign & Date
Name	Department	Sign & Date		

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RISK ASSESSMENT FOR PLANT EQUIPMENTS

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 GAPs 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 GAPs in Qualification Documents.

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

Approved By:
Head QA
(Sign & Date)