



INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VACUUM CLEANER

**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
VACUUM CLEANER**

EQUIPMENT ID. No.	
LOCATION	Warehouse
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	NIL



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VACUUM CLEANER



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PROTOCOL CONTENTS

S.No.	TITLE	PAGE No.
1.0	Pre-Approval	3
2.0	Objective	4
3.0	Scope	4
4.0	Responsibility	5
5.0	Equipment Details	6
6.0	System Description	6-10
7.0	Pre-Qualification Requirements	10
8.0	Critical Variables to be Met	11-22
9.0	References	23
10.0	Documents to be Attached	23
11.0	Deviation from Pre-Defined Specification, If Any	23
12.0	Change Control, If Any	23
13.0	Review (Inclusive of follow up action, If Any)	23
14.0	Conclusion	24
15.0	Recommendation	24
16.0	Abbreviations	25
17.0	Post Approval	26



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INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VACUUM CLEANER

1.0 PROTOCOL PRE – APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			
HEAD (WAREHOUSE)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



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2.0 OBJECTIVE:

- To provide documented evidence for the Installation Qualification of De dusting Tunnel in Warehouse.
- To confirm that the equipment and its components are installed as per the Specifications mentioned in the design qualification document and other requirements given by supplier.

3.0 SCOPE:

- The scope of this installation qualification protocol cum report is limited to qualification of Vacuum Cleaner (Make:) to be installed at Raw Material Receiving Bay.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Vacuum Cleaner.



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4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments shall be responsible for the overall compliance of this Protocol cum Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	<ul style="list-style-type: none">• Preparation, Review, Authorization and Compilation of the Installation Qualification Protocol cum Report.• Co-ordination with Production and Engineering to carryout Installation Qualification.• Monitoring of Installation Qualification Activity.• Post Approval of Qualification Protocol cum Report after Execution.
Warehouse	<ul style="list-style-type: none">• Review & Pre Authorization of Installation Qualification Protocol cum Report.• To Co-ordinate and support for Execution of Qualification study as per Protocol.• Post Approval of Installation Qualification Protocol Cum Report after Execution.
Engineering	<ul style="list-style-type: none">• Review & Pre Approval of Installation Qualification Protocol cum Report.• Co-ordination, Execution and technical support in Installation Qualification Activity.• Calibration of Process Instruments.• Responsible for Trouble Shooting (if occurs during execution).• Post Approval of Installation Qualification Protocol Cum report after Execution.



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5.0 EQUIPMENT DETAILS:

Equipment Name	De dusting Tunnel
Equipment ID.	
Manufacturer's Name	
Supplier's Name	
Model	
Serial Number	
Location of Installation	Raw Material Receiving Bay

6.0 SYSTEM DESCRIPTION:

Vacuum Cleaner is used for de-dusting the material containers at material receiving bay, the filtered air is delivered by the adjustable nozzles positioned on both sides and on the ceiling of the unit. The high velocity air jets remove most of the contamination dust from the outer surface of containers. The air is drawn through the HEPA & Pre-filters. The air flow rate and the nozzles position have been designed in order to assure that the pallet is completely invested by air jets.

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document.
- Electrical circuits diagram.
- Technical specification of equipment.

7.1.1 Procedure:

- Verify the above mentioned documents for availability, completeness and approval status.
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the IQ Protocol cum Report.

7.1.2 Acceptance Criteria:

- All the documents should be available, complete and approved by respective authorities.



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8.0 CRITICAL VARIABLES TO BE MET:

8.1 Installation Qualification Checklist:

INSTALLATION CHECKS	ACCEPTANCE CRITERIA	OBSERVATION (COMPLIES /NOT COMPLIES)	OBSERVED BY (ENGINEERING) SIGN/DATE
Grouting and Mounting	Should be properly grouted and mounted.		
Leveling	Should be properly balanced and leveled.		
Edges of parts	Metal parts should be properly ground without any sharp edges.		
Welding of Joints	Welding of joints should be without any welding burrs.		
Place of Installation	Raw Material Receiving Bay		
Room Condition	RH : NMT 55 % TEMP : NMT 25 °C		
Illumination	NLT 300 Lux		
Working space around the Equipment.	Should be sufficient for easy operation, cleaning, sanitation and maintenance.		

Checked By
Warehouse
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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Reviewed By
Manager QA
Sign/Date:



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8.1 VERIFICATION OF UTILITY REQUIREMENTS:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION (COMPLIES /NOT COMPLIES)	OBSERVED BY (ENGINEERING) SIGN/DATE
Electrical Supply	Voltage : 415 V Phase : 3 Phase Frequency : 50 Hz ± 10%. Power consumption : 6 kW max		
Room Condition	Temperature NMT 25 °C RH : NMT 55 %		

Checked By
Warehouse
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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Reviewed By
Manager QA
Sign/Date:



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8.2 Installation Checks For Technical Specification:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION (COMPLIES /NOT COMPLIES)	OBSERVED BY (ENGINEERING) SIGN/DATE
Machine Specification			
Model	CAS55		
Machine Number	2018040005		
Body Structure Working area (W x H x D)	1500 x 1500 x1300 mm		
HEPA Filter (Supply Air)			
Qty	01 No.		
Make	Hygieno		
Size	1220 x 610 x 69 mm		
Rating	H14		
Efficiency	99.995% down to 0.3mic.		
MOC of Frame	Aluminium		
Type	Box		
Pre-Filter			
Qty	01 No.		
Make	Hygieno		
Size	550 x 550 x 50 mm		
Filter Class	EU5		
Efficiency	95% down to 5mic.		
MOC of Frame	Aluminum		
Type	Flange		
Motor			
Qty	01 No.		
Make	Marathon		
Rated Power	3 HP, 2850 RPM		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION (COMPLIES /NOT COMPLIES)	OBSERVED BY (ENGINEERING) SIGN/DATE
Type	Belt Drive		
Blower			
Qty	01 Nos.		
Make	Nicotra		
Size	RLO 283		
Type	Plug Fan		

Checked By
Warehouse
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Verified By
Quality Assurance
Sign/Date:

Inference:

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Sign/Date:



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8.2 MATERIAL OF CONSTRUCTION:

Parts Name	ACCEPTANCE CRITERIA	OBSERVATION (Complies /Not Complies)	OBSERVED BY (ENGINEERING) SIGN/DATE
Outer Sheet	GI powder coated		
Inner Area	SS-matt finish		
Roller With Lockable Wheels	SS Steel		
Roller Frame	SS Frame		
Structure Of Roller	SS Steel		
Bottom Tray	GI Powder coated		
Dust Collector	GI Powder coated		
Filter Housing	GI		
Curtain for back	PVC Curtain		
Door	GI Powder coated		
Blower impeller	Aluminium		
Pipe	PVC		
Gasket	Neoprene		
Sealant	Silicon sealant		
PVC Strips	PVC		

Checked By
Warehouse
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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Reviewed By
Manager QA
Sign/Date:



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8.3 SAFETY FEACHURE & ALARM :

Critical Variables	Acceptance Criteria	OBSERVATION (Complies /Not Complies)	OBSERVED BY (ENGINEERING) SIGN/DATE
Joints	Welding of joints without any welding burrs		
Metal Parts	All the metal parts should be Properly grind without any sharp edges.		
Leveling and balancing	Vacuum Cleaner should be properly balanced & leveled		
Electrical wiring and earthing	Electrical wiring should be as per approved drawings. Single external Earthing to control machine (panel and motors) and operator should be provided		
Emergency Switch	Provided easy access position		

Checked By
Warehouse
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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Reviewed By
Manager QA
Sign/Date:



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9.0 REFERENCES:

- Design Qualification
- Vendor Documents

10.0 DOCUMENTS TO BE ATTACHED:

- Calibration certificates.
- Any other relevant documents.

11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION IF, ANY:

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12.0 CHANGE CONTROL, IF ANY:

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13.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

- cGMP : Current Good Manufacturing Practice
- VCC : Vacuum Cleaner
- HP : Horse Power
- Hz : Hertz
- MCB : Miniature circuit breaker
- mm : Millimeter
- NLT : Not less than
- NMT : Not More Than
- RH : Relative Humidity
- RPM : Revolution per minute
- SS : Stainless steel



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17.0 PROTOCOL POST- APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			
HEAD (WAREHOUSE)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			