DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR VACUUM CLEANER

DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR VACUUM CLEANER

CONTENTS

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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)			

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR VACUUM CLEANER

2.0 OBJECTIVE:

- To prepare the Design Qualification document for de dusting tunnel on basis of Design and Specification and information given by Supplier.
- To ensure that all Critical Aspects of Process/Product Requirement, cGMP and Safety have been considered in designing the equipment and are properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification of **De dusting Tunnel (Make: ……..)** to be installed at Raw Material Receiving Bay.
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.

4.0 PROJECT REQUIREMENTS:

To confirm that safe delivery of the equipment from the supplier site. To ensure that no un-authorized or unrecorded design modification shall take place.

If at any point in time, any change is desired in the mutually agreed design, change control procedure shall be followed and documented.

5.0 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	• Preparation, Review, Authorized and Compilation of the Design Qualification Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Review of Qualification Protocol cum Report after Execution. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity.
Warehouse	• Review of the Design Qualification Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Review of Qualification Protocol cum Report after Execution.
Engineering	• Review of the Design Qualification Protocol cum Report. • Assist in the Preparation of the Protocol cum Report. • To co-ordinate and support the Activity. • To assist in Verification of Critical Process Parameter, Drawings as per the Specification i.e. ➢ GA Drawing. ➢ Specification of the sub-components/bought out items, their Make, Model, Quantity and backup records/ brochures. ➢ Details of utilities. ➢ Identification of components for calibration. ➢ Material of construction of all components. ➢ Brief Process Description. ➢ Safety Features and Alarms. • Review of Design Qualification Protocol Cum Report after Execution.

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR VACUUM CLEANER

6.0 BRIEF EQUIPMENT 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 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification prepared for the manufacturer of equipment ensures complies with user requirement specification.

8.0 CRITICAL VARIABLES TO BE MET:

8.1 PROCESS/PRODUCT PARAMETERS:

Critical Variables	Acceptance Criteria	Reference
Application: Vacuum Cleaner is capable of removing dust particles from containers.	Vacuum Cleaner should meet the requirement to provide dust free containers.	Process Requirement
Working: Working of Vacuum Cleaner	To provide dust free environment.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Design Requirement

8.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:

Critical Variables	Acceptance Criteria	Reference
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	Single Phase 3 Wire Line Up To The Panel Board Terminal. Voltage- **230 V** Frequency- **50 Hz**	cGMP Requirement
Room Condition	Should be able to meet the requirement of clean environment.	Process Requirement

8.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

S.No.	Parameters	Acceptance criteria	Reference
1.	Body Structure		
	Working area (W x H x D)	1500 x 1500 x1300 mm	Design Requirement
2.	HEPA Filter (Supply Air)		
	Qty	01 No.	Design Requirement
	Make	Hygieno	Design Requirement
	Size	1220 x 610 x 69 mm	Design Requirement
	Rating	H14	Design Requirement
	Efficiency	99.995% down to 0.3mic.	Design Requirement
	MOC of Frame	Aluminum	Design Requirement
	Type	Box	Design Requirement
3.	Pre-Filter		
	Qty	01 No.	Design Requirement
	Make	Hygieno	Design Requirement
	Size	550 x 550 x 50 mm	Design Requirement
	Filter Class	EU5	Design Requirement
	Efficiency	95% down to 5mic.	Design Requirement
	MOC of Frame	Aluminum	Design Requirement
	Type	Flange	Design Requirement
4.	Motor		

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR VACUUM CLEANER

S.No.	Parameters	Acceptance criteria	Reference
	Qty	01 No.	Design Requirement
	Make	Marathon	Design Requirement
	Rated Power	3 HP, 2850 RPM	Design Requirement
	Type	Belt Drive	Design Requirement
5.	Blower		
	Qty	01 Nos.	Design Requirement
	Make	Nicotra	Design Requirement
	Size	RLO 283	Design Requirement
	Type	Plug Fan	Design Requirement

8.4 MATERIAL OF CONSTRUCTION:

S. No.	Parts name	Material of construction
1.	Outer Sheet	GI powder coated
2.	Inner Area	SS-matt finish
3.	Roller With Lockable Wheels	SS Steel
4.	Roller Frame	SS Frame
5.	Structure Of Roller	SS Steel
6.	Bottom Tray	GI Powder coated
7.	Dust Collector	GI Powder coated
8.	Filter Housing	GI
9.	Curtain for back	PVC Curtain
10.	Door	GI Powder coated
11.	Blower impeller	Aluminium
12.	Pipe	PVC
13.	Gasket	Neoprene
14.	Sealant	Silicon sealant
15.	PVC Strips	PVC

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR VACUUM CLEANER

8.5 SAFETY:

Critical Variables	Acceptance Criteria	Reference
Joints	Welding of joints without any welding burrs	Safety Requirement
Metal Parts	All the metal parts should be Properly grind without any sharp edges.	Safety Requirement
Leveling and balancing	Vacuum Cleaner should be properly balanced & leveled	Safety Requirement
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	Safety Requirement
Emergency Switch	Provided easy access position	GMP & Safety Requirement

8.6 VENDOR SELECTION:

Critical variables	Acceptance criteria	Reference
Selection of Vendor for supplying the Vacuum Cleaner.	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/financial), technical knowhow, quality standards, inspection of site, costing, feedback from market (customers already using the equipment)	Process Requirement

Checked By
Engineering
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date: ……

Inference:

……

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Reviewed By
Manager QA
Sign/Date: ……

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR VACUUM CLEANER

9.0 DOCUMENTS TO BE ATTACHED:

- Any other relevant documents.

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

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11.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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12.0 RECOMMENDATION:

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13.0 ABBREVIATIONS:

cGMP	:	Current Good Manufacturing Practice
Ltd.	:	Limited
QA	:	Quality Assurance
PO	:	Purchase Order
Kg	:	Kilogram
Hr	:	Hour
mm	:	Millimeter
SS	:	Stainless Steel
MOC	:	Material of Construction
GA	:	General Arrangement
STD	:	Standard
PVC	:	Polyvinyl Chloride

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14.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (WAREHOUSE)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			