



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR DEDUSTING TUNNEL

**DESIGN QUALIFICATION
PROTOCOL CUM REPORT
FOR
DEDUSTING TUNNEL**

DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	NIL



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR DEDUSTING TUNNEL

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PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

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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)			



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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.



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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, 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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.<ul style="list-style-type: none">➤ 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.



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5.0 PROJECT REQUIREMENTS:

To confirm that safe delivery of the equipment from the supplier site. To ensure that no unauthorized 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.

6.0 BRIEF EQUIPMENT DESCRIPTION:

De-dusting Tunnel 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.

De-dusting tunnel is made of AISI 304 stainless steel casing. It is constructed by cutting, hemming, bending, spot welding and bolt junctioning where necessary. The welded pieces are strengthened by subsequent silicon sealing.

The electric control panel is placed outside the box and it is easy to reach.

The filtered air is delivered by the adjustable nozzles positioned on both wall sides and on the ceiling of the unit. The high velocity air jets remove most of the contamination dust from the pallet that is positioned inside the box.

The air is drawn through the Pre & Fine-filter. 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.



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8.0 CRITICAL VARIABLES TO BE MET:

8.1 PROCESS/PRODUCT PARAMETERS:

Critical Variables	Acceptance Criteria	Reference
Application: Dedusting tunnel is capable of removing dust particles from containers.	Dedusting Tunnel should meet the requirement to provide dust free containers.	Process Requirement
Working: Working of Dedusting Tunnel	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



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8.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

S.No.	Particular	Specification
1.	Model No.	CAS-55
2.	Working Dimension (W x H x D)	1500 x 1500 x 1300 mm
3.	Fine Filter (Supply Air)	
	Qty.	01 No.
	Make	Hygieno
	Size	1220 x 610 x 69 mm
	Rating	EU 7
	Efficiency	95% down to 3 micron
	MOC of Frame	Aluminium
	Type	Box
4.	Pre-Filter	
	Qty.	01 No.
	Make	Hygieno
	Size	550 x 550 x 50 mm
	Filter Class	EU 5
	Efficiency	95% down to 5 micron
	MOC of Frame	Aluminum
	Type	Flange
5.	Motor	
	Qty.	01 No.
	Make	Cromptron
	Rated Power	3 HP, 2850 RPM
	Type	Belt Drive
6.	Blower	
	Qty.	01 Nos.
	Make	Nicotra
	Size	RLO 2831
	Type	Plug Fan
7.	Exhaust Fan	
	Qty.	01 Nos.
	Make	Chemietron
	Size	12 inch Dia. With 0.5 H.P. motor



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S.No.	Particular	Specification
	Type	Exhaust Fan
8.	Magnehelic gauge	
	Qty.	01 No.
	Make	Dwyer
	Range	0-10 mm of water

Checked By
Engineering
Sign/Date: _____

Verified By
Quality Assurance
Sign/Date: _____

Inference:

Reviewed By
Manager QA
Sign/Date: _____

8.4 MATERIAL OF CONSTRUCTION:

S. No.	Parts name	Material of construction
1.	Main Unit	SS-304
2.	Blower Body	GI powder coated
3.	Filter Housing	GI powder coated

Checked By
Engineering
Sign/Date: _____

Verified By
Quality Assurance
Sign/Date: _____

Inference:

Reviewed By
Manager QA
Sign/Date: _____



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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	Dedusting tunnel 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



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8.6 VENDOR SELECTION:

Critical variables	Acceptance criteria	Reference
Selection of Vendor for supplying the Dedusting tunnel.	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:



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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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DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR DEDUSTING TUNNEL

13.0 ABBREVIATIONS:

cGMP	:	Current Good Manufacturing Practice
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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QUALITY ASSURANCE DEPARTMENT

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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)			