



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

PROTOCOL No.:

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FOR
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DATE OF QUALIFICATION

SUPERSEDES No.

NIL



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1.0 PROTOCOL PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (WAREHOUSE)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

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2.0 OBJECTIVE:

- To prepare the Design Qualification document for Dedusting tunnel on basis of URS 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 **Dedusting Tunnel (Make:**).
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & ID's provided by Vendor shall be verified during Design Qualification.



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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, Approval and Compilation of Design Qualification Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity. • Review of Design Qualification Protocol cum Report after Execution.
Warehouse	<ul style="list-style-type: none"> • Review & Pre Approval of Design Qualification Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Post Approval of Design Qualification Protocol cum Report after Execution
Engineering	<ul style="list-style-type: none"> • Review & Pre Approval of 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 Required. ➤ Identification of components for calibration ➤ Material of construction of Product Contact Parts ➤ Brief Process Description ➤ Safety Features and Alarms • Post Approval of Design Qualification Protocol cum Report after Execution

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5.0 BRIEF EQUIPMENT DESCRIPTION:

Dedusting Tunnel is recommended where materials (on pallets) have to be moved from warehouse to class D areas according to GMP (Class ISO 8 according to ISO 14644-1). Dedusting 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 silicone sealing. The electric control panel is placed outside the box and it is easy to reachable.

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 pallet that is positioned inside the box.

The air is drawn through the EU-7 & EU-4 prefilters. The air flow rate and the nozzles position have been designed in order to assure that the pallet is completely invested by air jets. Light fixtures are installed on the ceiling panel of the shower for internal lighting.

6.0 EQUIPMENT SPECIFICATION:

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



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7.0 CRITICAL VARIABLES TO BE MET:

7.1 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

7.2 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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7.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

S.No.	Parameters	Acceptance criteria	Make
Body Structure			
1.	Overall Size (W x H x D)	1220 x 2000 x 1220 mm	Air fil
2.	Working area (W x H x D)	900 x 915 x 1220 mm	Air fil
3.	Curtain for back	PVC curtains	Wonder
4.	Roller	SS mat finish	Airfil
		25 numbers	
5.	Roller frame	SS frame	Airfil
6.	Roller weight capacity	250-300 kg	Airfil
7.	Nozzle	ST Steel	Airfil
		27 numbers	
		25 mm diameter	
8.	Gap B/W Per Roller	50 mm	GE
9.	Sealant	Epoxy based, Non Soluble	GE
Filter Details			
10.	Filters Series	EU-7 & EU-4	Airfil
		3 nos.	
Motor & Blower			
11.	Blower for main cabinet	Dynamically and Statically balanced, centrifugal type 24 HP, 3 PH	Dynamic
		2 nos.	
12.	Motor for roller	1 HP Motor, 3 PH	Kirloskar
		1 no.	
13.	Motor & blower for dust collector	2 HP Motor, 3 PH	Kirloskar
		1 no.	
14.	Air flow type	Turbulent flow	Kirloskar
15.	Air velocity per nozzle	At nozzle 5000 + FPM & in front of nozzle at 450 mm 2500 + FPM	-
16.	Indicator	230 v	Laptron
		3 nos.	
17.	Buzzer for both side	220 v	Airfil
		2 nos.	



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S.No.	Parameters	Acceptance criteria	Make
18.	Light Fixtures	36 W	Philips
		2 nos.	
19.	Electrical sockets	230 v,50 Hz, Single Phase	Roma
		3 nos.	
20.	Interlock automatic Sensor (For roller, suction blower & Blower for supply)	Photo sensor with interlocking with over load relay	Airfil
		1 no.	
21.	Door (With Handle, lock ,View Window)	GI Powder coated/Open with 180 Degree)	Airfil
22.	Reverse Forward Switch (Reversible Unit)	Belt is adjustable for reverse and forward movement	Airfil
23.	Electro Magnetic Interlocking	Door interlocked when closed	Airfil
24.	Water drainage valve	Drainage valve should be at the bottom of roller belt	Airfil

Checked By
Engineering
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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Reviewed By
Manager QA
Sign/Date:

7.4 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.	Structure Of Roller	SS Steel
5.	Bottom Tray	GI Powder coated
6.	Dust Collector	GI Powder coated
7.	Filter Housing	GI
8.	Pipe	PVC
9.	PVC Strips	PVC

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Verified By
Quality Assurance
Sign/Date:

Inference:

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Sign/Date:

7.5 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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Engineering
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Quality Assurance
Sign/Date:

Inference:

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7.6 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

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Reference: (1) User Requirement Specifications (URS).
 (2) Design & Functional Specifications provided by Vendor.

8.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Any other relevant documents.

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

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10.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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11.0 RECOMMENDATION:

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12.0 ABBREVIATIONS:

- cGMP : Current Good Manufacturing Practice
- DDT : Dedusting Tunnel
- GA : General Arrangement
- Hr : Hour
- Kg : Kilogram
- Ltd. : Limited
- mm : Millimeter
- MOC : Material of Construction
- PO : Purchase Order
- SS : Stainless Steel
- STD : Standard
- URS : User requirement specification.



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13.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (WAREHOUSE)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			