



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

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



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR DEDUSTING TUNNEL



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INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR DEDUSTING TUNNEL

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)			



INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR DEDUSTING TUNNEL

2.0 OBJECTIVE:

- To provide documented evidence for the Installation Qualification of De dusting Tunnel.
- 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 Dedusting Tunnel (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 Dedusting Tunnel.



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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:

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.



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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:



INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR DEDUSTING TUNNEL

8.2 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:



INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR DEDUSTING TUNNEL

8.3 EQUIPMENT VERIFICATION

S.No.	Particular	Specification	Observation
Body Structure			
1.	Model No.	CAS-55	
2.	Working Dimension (W x H x D)	1500 x 1500 x1300 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	Crompton	
	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		



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S.No.	Particular	Specification	Observation
	Qty.	01 Nos.	
	Make	Chemietron	
	Size	12 inch Dia. With 0.5 H.P. motor	
	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: _____



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8.4 SAFETY FEACHURE & ALARM :

Critical Variables	Acceptance Criteria	OBSERVATION (Complies /Not Complies)	OBSERVED BY (ENGINEERING) SIGN/DATE
Joins	Welding of joints without any welding burrs		
Metal Parts	All the metal parts should be Properly grind without any sharp edges.		
Leveling and balancing	Dedusting tunnel 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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INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR DEDUSTING TUNNEL

15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

- cGMP : Current Good Manufacturing Practice
- DDT : Dedusting Tunnel
- 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)			