INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
DEDUSTING TUNNEL

EQUIPMENT ID. No.	
LOCATION	**Raw Material Receiving Bay**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR DEDUSTING TUNNEL	PROTOCOL No.:

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PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR DEDUSTING TUNNEL	PROTOCOL No.:

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)			

2.0 OBJECTIVE:

- To provide documented evidence for the Installation Qualification of **Dedusting 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**.

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	• Initiation, Approval and Compilation of the Installation Qualification Protocol cum Report. • Co-ordination with Warehouse and Engineering to carryout Installation Qualification. • Monitoring of Installation Qualification Activity. • Post Approval of Qualification Protocol cum Report after Execution.
Warehouse	• Review & Pre Approval of Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol. • Post Approval of Qualification Protocol cum Report after Execution.
Engineering	• Review & Pre Approval of Protocol cum Report. • Co-ordination, Execution and technical support in Dedusting Tunnel Installation Qualification Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Qualification Protocol cum Report after Execution

5.0 EQUIPMENT DETAILS:

Equipment Name	Dedusting tunnel
Equipment	
Manufacturer's Name	Airfil Clean Room System Pvt. Ltd
Model	GMP Model
Supplier's Name	Airfil Clean Room System Pvt. Ltd
Location of Installation	Raw Material Receiving Bay

6.0 SYSTEM DESCRIPTION:

Dedusting 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.

The air is drawn through the EU-4 & EU-7 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.

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document
- Technical specification of equipment
- Calibration certificate of components
- Certificate of material of construction of components.

8.0 CRITICAL VARIABLES TO BE MET:

8.1 General Checks and Location Suitability:

Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Leveling	Should be properly balanced and leveled		
Edges of parts	Metal parts should be properly grind 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	General working condition		
Illumination in area	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: ……

8.2 Equipment Verification:

Installation Checks	Acceptance Criteria		Observation	Observed By (Engineering) Sign/Date
Equipment	Dedusting Tunnel			
ELECTRICAL INSTALLATION:				
Electricity	Voltage	230 V		
	Phases	3 Phase		
	Frequency	50 Hz		
Electrical connections have been provided and secured.	Should be provided & secured			
All components in the panel are properly secured	Should be properly secured			
All terminals are tightened	Should be tightened			
Earthing connection to control panel & equipment	Earthing connection to control panel & equipment should be provided.			

Checked By
(Warehouse)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

8.3 Installation Checks:

S. No.	Specification	Observation	Observed By (Engineering) Sign/Date
1.	Check the proper mechanical installation of Dedusting Tunnel.		
2.	Check the proper electrical installation of Dedusting Tunnel		
3.	Check the parts are working properly		
4.	Check the equipment is free from any defects		
5.	Check that all parts are getting lubricated		

Checked By
(Warehouse)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

8.4 MOC Verification List:

Parts name	Material of construction	Observation	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		

Checked By
(Warehouse)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

8.5 EQUIPMENT VERIFICATION

Parameters	Acceptance criteria	Observation	Observed by (Engineering) Sign/Date
Body Structure			
Overall Size (W x H x D)	1220 x 2000 x1220 mm		
Working area (W x H x D)	900 x 915 x 1220 mm		
Capacity	2000 CFM		
Motor & Blower			
Blower	Make : Dynamic Capacity : 1000 CFM Quantity : 2 Nos.		
Motor	**Main Motor** Make : Airfil **Motor For Roller** Make : Rotomac Capacity : 1 HP, 3 Phase Quantity : 1 Nos.		
Filter	**Fine filter** Make : Airfil Size : 915mm X 460mm X 50mm Quantity : 1 Nos. **Pre filter** Make : Airfil clean room system Pvt. Ltd Type : Box Type Size : 450mm X 450mm X 50mm Quantity : 1 Nos. Media : ALEXP + 3 HDPE + ALEXP MIC- NYLON		

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR DEDUSTING TUNNEL	PROTOCOL No.:

Parameters	Acceptance criteria	Observation	Observed by (Engineering) Sign/Date
	+ 250 D + NYLON Efficiency : 95% DOWN TO 5µ		
Nozzles	DIA : 25 mm Quantity : 32 Nos.		
Accessories	**Electrical fitting** Make : ROMA **Contractor** Make : Telemechanic **Electric circuit** Make : Airfil clean room system **Electro magnet** Make : Airfil **Photo –Sensor** Make : Autonic **Indicator** Make : Lutron		

Checked By
(Warehouse)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

8.6 Supporting Utilities:

Utility Description	Properly Connected And Identified	Deviation	Observed By Engineering Sign/Date
Electric power supply			
Earthing			

8.7 Safety:

Checks	Acceptance Criteria	Observation	Observed By Engineering Sign/Date
Well embedded equipment	For proper safety.		
Electrical wiring and Earthing	Electrical wiring should be as per approved drawings. Double external earthing to control machine (panel and motors).		
Start On/Off switch: To stop the process immediately	Should be provided For equipment and operator safety		
MCB for electrical overload	Should be properly installed		

Checked By
(Warehouse)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

9.0 REFERENCES:

- Design Qualification.

10.0 DOCUMENTS TO BE ATTACHED:

- Calibration certificates
- Operation and Maintenance Manual

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:

No.	:	Number
cGMP	:	Current Good Manufacturing Practices
cGEP	:	Current Good Engineering Practices
EU	:	European Union
QA	:	Quality Assurance
IQ	:	Installation Qualification
Amp.	:	Ampere
MOC	:	Material of construction
HP	:	Horse power
KW	:	Kilo watt
SS	:	Stainless steel
ID.	:	Identification
Kg	:	Kilo gram
Ltrs	:	Liters
mm	:	Millimeter

17.0 POST APPROVAL:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

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

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			