



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

<b>EQUIPMENT ID. No.</b>	
<b>LOCATION</b>	<b>Warehouse Quarantine</b>
<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDES PROTOCOL No.</b>	<b>NIL</b>



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

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

**1.0 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)			



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

**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: Airfil Clean Room System Pvt. Ltd)** to be installed in the Quarantine.
- 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**.



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR 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:

<b>DEPARTMENTS</b>	<b>RESPONSIBILITIES</b>
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Initiation, Authorization, Approval and Compilation of the Installation Qualification Protocol cum Report.</li><li>• Co-ordination with Production and Engineering to carryout Installation Qualification.</li><li>• Monitoring of Installation Qualification Activity.</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Review &amp; Pre Approval of Protocol cum Report.</li><li>• To Co-ordinate and support for Execution of Qualification study as per Protocol.</li><li>• Post Approval of Qualification Protocol after Execution.</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review &amp; Pre Approval of Protocol cum Report.</li><li>• Co-ordination, Execution and technical support in <b>Dedusting Tunnel</b> Installation Qualification Activity.</li><li>• Calibration of Process Instruments.</li><li>• Responsible for Trouble Shooting (if occurs during execution).</li><li>• Post Approval of Qualification Protocol after Execution</li></ul>



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

**5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	Dedusting tunnel
<b>Equipment</b>	
<b>Manufacturer's Name</b>	Airfil Clean Room System Pvt. Ltd
<b>Model</b>	GMP Model
<b>Supplier's Name</b>	Airfil Clean Room System Pvt. Ltd
<b>Location of Installation</b>	Warehouse Quarantine

**6.0 SYSTEM 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.



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

**7.0 PRE – QUALIFICATION REQUIREMENTS:**

**7.1 Verification of Documents:**

- Executed and approved design qualification document
- Piping and instrumentation diagram (P& ID)
- Electrical circuits diagram
- Technical specification of equipment
- Calibration certificate of components
- Certificate of material of construction of components.

**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.



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

**8.0 CRITICAL VARIABLES TO BE MET:**

**8.1 General Checks and Location Suitability:**

<b>Installation Checks</b>	<b>Acceptance Criteria</b>	<b>Observation</b>	<b>Observed By (Engineering) Sign/Date</b>
<b>Leveling</b>	Should be properly balanced and leveled		
<b>Edges of parts</b>	Metal parts should be properly grind without any sharp edges		
<b>Welding of Joints</b>	Welding of joints should be without any welding burrs		
<b>Place of Installation</b>	Warehouse Quarantine		
<b>Room Condition</b>	General working condition		
<b>Illumination in area</b>	NLT 300 Lux		
<b>Working space around the equipment</b>	Should be sufficient for easy operation, cleaning, sanitation and maintenance		

**Checked By  
(Production)**  
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 Equipment Verification:**

Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
<b>Equipment</b>	Dedusting Tunnel		
<b>Model</b>	GMP Model		

**ELECTRICAL INSTALLATION:**

Electricity	Voltage	415 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.			

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**Verified By**  
**(Quality Assurance)**  
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**Reviewed By**  
**(Manager QA)**  
**Sign/Date:** .....



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

**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		

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**(Quality Assurance)**  
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**(Manager QA)**  
**Sign/Date:** .....



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

**8.4 MOC Verification List:**

<b>Component</b>	<b>MOC</b>	<b>Observation</b>	<b>Observed by (Engineering) Sign/Date</b>
<b>MOC of outer sheet</b>	GI powder coated		
<b>MOC of inner area</b>	SS-matt finish		
<b>MOC of Roller</b>	SS Steel		
<b>MOC of Structure of roller</b>	SS Steel		
<b>MOC of Bottom Tray</b>	GI Powder coated		
<b>MOC of Dust Collector</b>	GI Powder coated		
<b>MOC for filter housing</b>	GI		

**Checked By  
(Production)  
Sign/Date: .....**

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(Quality Assurance)  
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(Manager QA)  
Sign/Date: .....**



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

**8.5 EQUIPMENT VERIFICATION**

S. No.	Parameters	Acceptance criteria	Observation
<b>Body Structure</b>			
1.	<b>Overall Size (W x H x D)</b>	1220 x 2000 x1220 mm	
2.	<b>Working area (W x H x D)</b>	900 x 915 x 1220 mm	
3.	<b>Curtain for back</b>	PVC curtains	
4.	<b>Roller</b>	SS mat finish	
		25 numbers	
5.	<b>Roller frame</b>	SS frame	
6.	<b>Roller weight capacity</b>	250-300 kg	
7.	<b>Nozzle</b>	ST Steel	
		27 numbers	
		25 mm diameter	
8.	<b>Gap B/W Per Roller</b>	50 mm	
9.	<b>Sealant</b>	Epoxy based, Non Soluble	
<b>Filter Details</b>			
10.	<b>Filters Series</b>	EU-7 & EU-4	
		3 nos.	
<b>Motor &amp; Blower</b>			
11.	<b>Blower for main cabinet</b>	Dynamically and Statically balanced, centrifugal type 24 HP, 3 PH	
		2 nos.	
12.	<b>Motor for roller</b>	1 HP Motor, 3 PH	
		1 no.	
13.	<b>Motor &amp; blower for dust collector</b>	2 HP Motor, 3 PH	
		1 no.	
14.	<b>Air flow type</b>	Turbulent flow	
15.	<b>Air velocity per nozzle</b>	At nozzle 5000 + FPM & in front of nozzle at 450 mm 2500 + FPM	
16.	<b>Indicator</b>	230 v	
		3 nos.	



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

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S. No.	Parameters	Acceptance criteria	Observation
17.	<b>Buzzer for both side</b>	220 v	
		2 nos.	
18.	<b>Light Fixtures</b>	36 W	
		2 nos.	
19.	<b>Electrical sockets</b>	230 v,50 Hz, Single Phase	
		3 nos.	
20.	<b>Interlock automatic Sensor (For roller, suction blower &amp; Blower for supply)</b>	Photo sensor with interlocking with over load relay	
		1 no.	
21.	<b>Door (with handle, lock, view window)</b>	GI powder coated/open with 180 degree	
22.	<b>Reverse forward switch (Reversible unit)</b>	Belt is adjustable for reverse and forward movement	
23.	<b>Door interlocked when closed</b>	Door interlocked when closed	
24.	<b>Reverse forward switch</b>	Belt shows forward and reverse movement	
25.	<b>Electromagnetic interlocking</b>	Doors interlocked when closed	
26.	<b>Water Drainage valve</b>	Drainage valve should be at the bottom of roller belt	

**Checked By  
(Production)**

**Sign/Date:** .....

**Verified By  
(Quality Assurance)**

**Sign/Date:** .....

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**Reviewed By  
(Manager QA)**

**Sign/Date:** .....



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

**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 sifting		
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		

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**(Production)**  
**Sign/Date:** .....

**Verified By**  
**(Quality Assurance)**  
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**Reviewed By**  
**(Manager QA)**  
**Sign/Date:** .....



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

**9.0 REFERENCES:**

**The Principle Reference is the following:**

- Master Validation Plan
- Schedule-M – “Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products.”
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2 – Good Manufacturing Practices and Inspection.

**The following references are used to give addition guidance:**

- FDA/ISPE Baseline Pharmaceutical Engineering Guide-Volume 5:- Commissioning and Qualification Guide, First Edition/March 2001.
- Code of Federal Regulations (CFR), Title 21, Part 210, Current Good Manufacturing Practice (cGMP) in Manufacturing, Processing, Packing, or Holding of Drugs, Beta. April 1, 1998.
- Code of Federal Regulations (CFR), Title 21, Part 211, Current Good Manufacturing Practice (cGMP) for Finished Pharmaceuticals, April 1, 1998.
- EU Guide to Good Manufacturing Practice, Part 4, 1997.
- European Commission’s working party on control of medicines and inspections document, Validation Master Plan, Design Qualification, Installation & Operational Qualification, Non Sterile Process Validation, Cleaning Validation, October 1999.
- GMP Guide, Validation of Automated Systems in Pharmaceutical Manufacture, Version 4.0, December 2001.

**10.0 DOCUMENTS TO BE ATTACHED:**

- Technical details for Equipment Requirement with Engineering Drawings.
- Certificate of MOC
- Calibration certificates
- Operation and Maintenance Manual



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

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

**14.0 CONCLUSION:**

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**15.0 RECOMMENDATION:**

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

**16.0 ABBREVIATIONS:**

Sr.	:	Senior
No.	:	Number
WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
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
NLT	:	Not less than
HP	:	Horse power
KW	:	Kilo watt
SS	:	Stainless steel
ID.	:	Identification
Kg	:	Kilo gram
Ltrs	:	Liters
mm	:	Mili meter



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

**17.0 POST 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)			