



# **PERFORMANCE QUALIFICATION PROTOCOL FOR DEDUSTING TUNNEL**

<b>EQUIPMENT ID. No.</b>	
<b>LOCATION</b>	<b>Receiving Bay</b>
<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDES PROTOCOL No.</b>	



**PERFORMANCE QUALIFICATION PROTOCOL FOR DEDUSTING TUNNEL**

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**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**PERFORMANCE QUALIFICATION PROTOCOL FOR DEDUSTING TUNNEL**

**1.0 PROTOCOL 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)			



## PERFORMANCE QUALIFICATION PROTOCOL FOR DEDUSTING TUNNEL

### 2.0 OBJECTIVE:

- To provide documented evidence that the Equipment is performing as per the parameter defined in operational qualification and that it gives result as per the predetermined acceptance criteria.
- To demonstrate that the system will operate reproducibly and consistently within its operating range.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.
- The document also provides the observed and obtained values indicating compliance to the PQ Protocol.

### 3.0 SCOPE:

- The Protocol covers all aspects of Performance Qualification for the De-dusting tunnel.
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.

### 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:

DEPARTMENTS	RESPONSIBILITIES
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Preparation, Review, Approval and Compilation of the Performance Qualification Protocol cum Report.</li><li>• Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity</li><li>• Monitoring of Performance Qualification.</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Review of Protocol cum Report.</li><li>• To co-ordinate and support Performance Qualification Activity.</li></ul>
<b>Quality Control</b>	<ul style="list-style-type: none"><li>• Review of Protocol cum Report</li><li>• Analytical Support (Microbiological Testing / Analysis)</li></ul>



**PERFORMANCE QUALIFICATION PROTOCOL FOR DEDUSTING TUNNEL**

**5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	De dusting Tunnel
<b>Equipment ID.</b>	
<b>Manufacturer's Name</b>	
<b>Supplier's Name</b>	
<b>Model</b>	
<b>Serial Number</b>	
<b>Location of Installation</b>	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.

**7.0 REASON FOR QUALIFICATION:**

Newly Installed.

**8.0 SITE OF STUDY:**

Warehouse, receiving bay.

**9.0 FREQUENCY OF QUALIFICATION:**

- Once in every five years  $\pm$  one month.
- After any major breakdown or after major modification.
- After Change of Location



**PERFORMANCE QUALIFICATION PROTOCOL FOR DEDUSTING TUNNEL**

**10.0 PRE-QUALIFICATION REQUIREMENTS:**

**10.1 Verification of Documents:**

S.No.	Document Name	Document/SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (Quality Assurance) Sign/Date
1.	DQ Protocol Cum Report				
2.	IQ Protocol Cum Report				
3.	OQ Protocol Cum Report				
4.	PQ Protocol				
5.	SOP for operating & Cleaning of De-dusting Tunnel.				
6.	SOP for Preventive Maintenance of De-dusting Tunnel				

**10.2 Training of Qualification Team:**

- All the persons involved in the execution of Qualification Protocol must be trained in all aspects of the qualification activity including the test methodology, acceptance criteria and safety precautions to be followed during working at service floor.

**10.3 Calibration of all Components of System and Test Instruments:**

- Calibration of all the instruments used for Re-qualification should be mentioned along with Calibration Certificates.

**11.0 TESTS AND CHECKS:**

**11.1 EVALUATION OF AIR VELOCITY:**

**11.1.1 Objective:**

- To verify the Average Air Flow Velocity across the filter in De-dusting tunnel.

**11.1.2 Equipment and Instruments**

- Vane type Anemometer/Pitot Tube and Manometer/Hot wire anemometer.



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### **11.1.3 Procedure:**

- Measure airflow velocities at the all hole of nozzles of de dusting tunnel
- Measurement time at each location should be at least 10-second duration and the values should be recorded.

### **11.1.4 Acceptance Criteria:**

- NLT 2000 FPM shall be maintained and measured at face of each nozzles.

## **11.2 DIFFERENTIAL PRESSURE OF DE-DUSTING TUNNEL:**

### **11.2.1 Objective:**

- To demonstrate that the air system is capable to delivering sufficient air volume and maintain Pressure Differential in de-dusting tunnel.

### **11.2.2 Equipment and Instrument:**

- Calibrated Magnehelic Gauge.

### **11.2.3 Procedure:**

- Operate the De-dusting tunnel system about 15 minute prior to recording the Differential Pressure.
- Measure and record the Differential Pressure three times after 30 minutes interval.

### **11.2.4 Acceptance Criteria:**

- Differential pressure across the filter in De-dusting tunnel shall be in the range of (4-10 mm of water)

### **11.2.5 Observation:**

- Record the observations in performance qualification report.

## **11.3 DUST CHALLENGE TEST OF CONTAINER:-**

### **11.3.1 Objective:**

- To demonstrate that the air system is capable to delivering sufficient air volume and clean the Container from dust.

### **11.3.2 Procedure:**

- Start the De-dusting tunnel system about 15 minute before start the test.



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- Pass the 05 dirty containers from outside with dust particle thorough de dusting tunnel.
- Take observation from inner side of de dusting tunnel.

**11.3.3 Acceptance Criteria:**

The entire container should be free from dust particle

**11.3.4 Observation:**

- Record the observations in performance qualification report.

**11.4 FREE MOVEMENT OF CONTAINER:-**

**11.4.1 Procedure:** To demonstrate the performance of smooth running of De-dusting conveyor tunnel, conveying bulk stuff through tunnel. Tartan the movement of stuff whether easily moving or not.

**11.4.2 Evaluation**

S.No.	Weight of Container (Kgs)	Free movement of Container YES/NO
1		
2		
3		
4		
5		

**12.0 CHECKLIST OF ALL TESTS & CHECKS:**

S.No.	Name of Test or Check	Acceptance Criteria
1.	Air Velocity Measurement	NLT 2000 FPM
2.	Differential pressure across the filter	4-10 Pascal
3.	Dust Challenge Test	Container free from dust particle
4.	Free Movement of Container	Easily Moving





**PERFORMANCE QUALIFICATION PROTOCOL FOR DEDUSTING TUNNEL**

**13.0 REFERENCES:**

**The Principle Reference is the following:**

- Validation Master 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.

**14.0 DOCUMENTS TO BE ATTACHED:**

Any Other Relevant Documents

**15.0 NON COMPLIANCE:**

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**16.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:**

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**17.0 CHANGE CONTROL, IF ANY:**

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**PERFORMANCE QUALIFICATION PROTOCOL FOR DEDUSTING TUNNEL**

**18.0 ABBREVIATIONS:**

No.	:	Number
WHO	:	World Health Organization
cGMP	:	Current Good Manufacturing Practices
EU	:	European Union
QA	:	Quality Assurance
IQ	:	Installation Qualification
OQ	:	Operational Qualification
DDT	:	Dedusting Tunnel
NLT	:	Not less than
ID.	:	Identification
Kg	:	Kilo gram
mm	:	Millimeter