OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR DEDUSTING TUNNEL

EQUIPMENT ID. No.	
LOCATION	Receiving Bay
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	NIL

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

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

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)			

2.0 OBJECTIVE:

- To verify that the equipment operates in accordance with the design and user requirements as defined by set acceptance criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of Dedusting Tunnel and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The scope of this Operational qualification protocol cum report is limited to qualification of **Dedusting Tunnel (Make: ……..)** to be installed in the receiving Bay Ground Floor.
- This Protocol will define the methods and documentation used to perform OQ activity the Dedusting Tunnel for OQ. Successful completion of this Protocol will verify that Dedusting Tunnel meet all acceptance criteria and ready for Performance Qualification.

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	• Preparation, Approval and Compilation of the Operational Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Operational Qualification. • Monitoring of Operational Qualification Activity.
Production	• Review & Pre Approval of Operational Qualification Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol. • Post Approval of Operational Qualification Protocol cum Report after Execution.
Engineering	• Review & Pre Approval of Operational Qualification Protocol cum Report. • Co-ordination, Execution and technical support in Dedusting Tunnel Operational Qualification Activity. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Operational 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	cGMP Model
Supplier's Name	Airfil Clean Room System Pvt. Ltd
Location of Installation	Receiving Bay Warehouse

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.

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of documents:

The results of any tests should meet the limits and acceptance criteria specified in the test documents.

Any deviations or issues should be rectified and documented prior to OQ commencing.

S.No.	Document Name	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By QA Officer/Exe. Sign/Date
1.	DQ Protocol Cum Report			
2.	IQ Protocol Cum Report			
3.	SOP for Operation & Cleaning of De-dusting Tunnel.			
4.	SOP for Preventive Maintenance of De-dusting Tunnel			

Checked By
Engineering
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date: ……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Operational and Functional Checks:

Operate the Dedusting Tunnel as per Manufacturer's Manual/SOP and Check for the following functions of the equipment. The Equipment should function as desired.

S.No	Operation	Observation	Observed By (Engineering) Sign/Date
1.	Verify all the curtains are properly fixed		
2.	Verify all the nozzles are working properly		
3.	Verify the door is properly fixed		
4.	All electrical (socket lights) are operating		
5.	No abnormal sound is found under working condition		
6.	Buzzer is working properly		
7.	Light glows when switched "ON"		
8.	Door should open and close as per requirement		
9.	Reverse & Forward movement of roller belt		
10.	Water Drainage valve should be free flowing, water should not accumulate		

Checked By
Engineering
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date: ……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

8.2 Power Failure Verification:

Item	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Main Power shut down	Equipment stops in safe and secure condition		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions.		

Checked By
Engineering
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date: ……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

9.0 REFERENCES:

- 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.

10.0 DOCUMENTS TO BE ATTACHED:

- Operation And Maintenance Manual
- Any Other Relevant Documents

11.0 DEVIATION FROM PREDEFINED 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:

cGMP	:	Current Good Manufacturing
EQ	:	Equipment
HP	:	Horse power
ID.	:	Identification
DQ	:	Design Qualification
IQ	:	Installation Qualification
Kg	:	Kilo gram
KW	:	Kilo watt
Ltrs	:	Liters
MCB	:	Miniature circuit break
mm	:	Millimeter
MOC	:	Material of construction
NLT	:	Not less than
No.	:	Number
WHO	:	World Health Organization

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)			