OPERATIONAL QUALIFICATION

PROTOCOL CUM REPORT

FOR

DEDUSTING TUNNEL

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

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR DEDUSTING TUNNEL

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OPERATIONAL 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)			

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR DEDUSTING TUNNEL

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: Airfil Clean Room System Pvt. Ltd)** to be installed in the Raw Material Receiving Bay.
- This Protocol will define the methods and documentation used to perform OQ activity of Dedusting Tunnel successful, completion of this Protocol will verify that Dedusting Tunnel meet all acceptance criteria and ready for warehouse use.

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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	• Preparation, Approval and Compilation of the Operational Qualification Protocol cum Report. • Co-ordination with Warehouse and Engineering to carryout Operational Qualification. • Monitoring of Operational Qualification Activity. • Post approval of Operational Qualification Protocol Cum Report.
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.
Engineering	• Review & Pre Approval of Protocol cum Report. • Co-ordination, Execution and technical support in Dedusting Tunnel Operational Qualification Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Qualification Protocol Cum Report.

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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.

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR DEDUSTING TUNNEL

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- DQ Protocol Cum Report
- IQ Protocol cum Report
- SOP for operation & Cleaning of Dedusting Tunnel
- SOP for Preventive Maintenance of Dedusting Tunnel

8.0 CRITICAL VARIABLES TO BE MET:

8.1 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	Document/SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date
1.	DQ Protocol Cum Report			
2.	IQ Protocol Cum Report			
3.	SOP for operation & Cleaning of Dedusting Tunnel.			
4.	SOP for Preventive Maintenance of Dedusting Tunnel			

Checked By
(Warehouse)
Sign/Date: ……

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

Inference:

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

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR DEDUSTING TUNNEL

8.2 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.	No abnormal sound is found under working condition		
5.	Buzzer is working properly		
6.	Door should open and close as per requirement		
7.	Reverse & Forward movement of roller belt		
8.	Water Drainage valve should be free flowing, water should not accumulate		

Checked By
(Warehouse)
Sign/Date: ……

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

Inference:

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

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR DEDUSTING TUNNEL

8.2.1 Air Velocity Measurement

Test instrument details:

Instrument Name	
Make/ Model / Type	
Calibration Date	
Calibration Due Date	

Nozzle	1	2	3	4	5	6	7	8	9
Air Velocity in (Ft/min)									
Nozzle	10	11	12	13	14	15	16	17	18
Air Velocity in (Ft/min)									
Nozzle	19	20	21	22	23	24	25	26	27
Air Velocity in (Ft/min)									
Nozzle	28	29	30	31	32				
Air Velocity in (Ft/min)									
Acceptance criteria: Average Air Velocity NLT 200 feet/minute									

Checked By
(Warehouse)
Sign/Date: ……

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

Inference:

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

8.3 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
(Warehouse)
Sign/Date: ……

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

Inference:

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

9.0 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."
- EU Guide to Good Manufacturing Practice, Part 4, 30 March 2015.

10.0 DOCUMENTS TO BE ATTACHED:

- 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:

WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
cGMP	:	Current Good Manufacturing Practices
EU	:	European Union
QA	:	Quality Assurance
IQ	:	Installation Qualification
OQ	:	Operational Qualification
EQ	:	Equipment
DDT	:	Dedusting Tunnel
CFM	:	Cubic feet per minute
SOP	:	Standard Operating Procedure

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)			