



PERFORMANCE QUALIFICATION REPORT FOR DEDUSTING TUNNEL

**PERFORMANCE QUALIFICATION
REPORT
FOR
DEDUSTING TUNNEL**

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



PERFORMANCE QUALIFICATION REPORT FOR DEDUSTING TUNNEL

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PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FOR DEDUSTING TUNNEL

1.0 REPORT PRE-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)			



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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 report 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 Report.

Departments	Responsibilities
Quality Assurance	<ul style="list-style-type: none">• Preparation, Review, Approval and Compilation of the Performance Qualification Report.• Protocol Training Record.• Co-ordination with Warehouse and Engineering to carryout Performance Qualification Activity.• Monitoring of Performance Qualification.
Warehouse	<ul style="list-style-type: none">• Review & Approval of Report.• To Execute the Performance Qualification Activity.
Engineering	<ul style="list-style-type: none">• Review & Approval of Report.• Co-ordination, Execution and technical support in Qualification Activity.• Responsible for Trouble shooting (if occurs during execution).



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5.0 EQUIPMENT DETAILS:

Equipment Name	De dusting Tunnel
Equipment	
Manufacturer's Name	
Model	
Serial Number	
Supplier's Name	
Location of Installation	Raw Material Receiving Bay

6.0 PRE – QUALIFICATION REQUIREMENTS:

6.1 Verification of Documents:

S.No.	Document Name	Document / SOP No	Completed (Yes/No)	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			

6.2 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.



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7.0 TESTS AND CHECKS:

7.1 AIR VELOCITY MEASUREMENT:

TEST INSTRUMENT DETAILS:

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

OBSERVATION AND RESULTS:

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)									

Acceptance criteria: Air Velocity NLT 2000 feet/minute

Checked By:
(Warehouse)
Sign & Date:.....

Verified By:
(Quality Assurance)
Sign & Date:.....

Inference:

.....
.....
.....
.....

Reviewed By
(Manager QA)
(Sign & Date:



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7.2 DIFFERENTIAL PRESSURE RECORD:

Instruments ID. No.	
Date of Calibration	
Calibration due date	
Acceptance Criteria	

Date	Differential Pressure	Observation	
		Time	mm of water

Checked By:
(Warehouse)
Sign & Date:.....

Verified By:
(Quality Assurance)
Sign & Date:.....

Inference:

.....
.....
.....
.....

Reviewed By
(Manager QA)
(Sign & Date:



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7.3 DUST CHALLENGE TEST OF CONTAINER:

S. No.	Container	Observation
1		
2		
3		
4		
5		

Verified By:
(Quality Assurance)
Sign & Date:.....

Inference:

.....
.....
.....

Reviewed By
(Manager QA)
(Sign & Date:



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7.4 FREE MOVEMENT OF CONTAINER :-

S.No.	Weight of Container (Kg)	Free movement of Container Yes/No
1		
2		
3		
4		
5		

Verified By:
(Quality Assurance)
Sign & Date:.....

Inference:

.....
.....
.....

Reviewed By
(Manager QA)
(Sign & Date:



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8.0 CHECKLIST FOR TESTS & CHECKS:

S.No.	Name of Test or Check	Execution (Yes/ No)	Remark	Verified By (Sign & Date)
1.	Air Velocity Measurement			
2.	Differential Pressure Record			
3.	Dust challenge test of Container			
4.	Free Movement of Container			

Verified By:
(Quality Assurance)
Sign & Date:.....

Inference:

.....
.....
.....

Reviewed By
(Manager QA)
(Sign & Date:

9.0 DOCUMENTS ATTACHED:

- Calibration Certificate of test Instruments.
- Any Other Relevant Documents.

10.0 NON COMPLIANCE:

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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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PERFORMANCE QUALIFICATION REPORT FOR DEDUSTING TUNNEL

16.0 ABBREVIATIONS:

No.	:	Number
FPM	:	Feet Per Minute
cGMP	:	Current Good Manufacturing Practices
QA	:	Quality Assurance
IQ	:	Installation Qualification
OQ	:	Operational Qualification
DDT	:	De-dusting Tunnel
NLT	:	Not less than
ID.	:	Identification
Kg	:	Kilo gram



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17.0 REPORT POST 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)			