



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
REPORT
FOR
DEDUSTING TUNNEL**

PROTOCOL No.:

**PERFORMANCE QUALIFICATION
REPORT
FOR
DEDUSTING TUNNEL**

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



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
REPORT
FOR
DEDUSTING TUNNEL**

PROTOCOL No.:

REPORT CONTENTS

S.No.	Title	Page No.
1.0	Report Pre-Approval	3
2.0	Objective	4
3.0	Scope	4
4.0	Responsibility	4
5.0	Equipment Details	5
6.0	Pre-Qualification Requirements	5
7.0	Tests & Checks	6-9
8.0	Checklist of all Tests & Checks	10
9.0	Documents Attached	10
10.0	Non Compliance	10
11.0	Deviation From Pre-Defined Specification, If Any	11
12.0	Change Control, If Any	11
13.0	Review (Inclusive Of Follow Up Action, If Any)	11
14.0	Conclusion	11
15.0	Recommendation	11
16.0	Abbreviations	12
17.0	Report Post Approval	13



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
REPORT
FOR
DEDUSTING TUNNEL**

PROTOCOL No.:

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)			



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
REPORT
FOR
DEDUSTING TUNNEL**

PROTOCOL No.:

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).



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
REPORT
FOR
DEDUSTING TUNNEL**

PROTOCOL No.:

5.0 EQUIPMENT DETAILS:

Equipment Name	De dusting Tunnel
Equipment	
Manufacturer's Name	
Model	
Serial Number	
Supplier's Name	Chemietron Clean Tech Pvt. Ltd.
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.



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
REPORT
FOR
DEDUSTING TUNNEL**

PROTOCOL No.:

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:



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
REPORT
FOR
DEDUSTING TUNNEL**

PROTOCOL No.:

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:



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
REPORT
FOR
DEDUSTING TUNNEL**

PROTOCOL No.:

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:)



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
REPORT
FOR
DEDUSTING TUNNEL**

PROTOCOL No.:

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:



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
REPORT
FOR
DEDUSTING TUNNEL**

PROTOCOL No.:

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:

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



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
REPORT
FOR
DEDUSTING TUNNEL**

PROTOCOL No.:

11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

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

12.0 CHANGE CONTROL, IF ANY:

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

13.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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

14.0 CONCLUSION:

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

15.0 RECOMMENDATION:

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



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
REPORT
FOR
DEDUSTING TUNNEL**

PROTOCOL No.:

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



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
REPORT
FOR
DEDUSTING TUNNEL**

PROTOCOL No.:

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)			