PERFORMANCE QUALIFICATION REPORT FOR VERTICAL LAMINAR AIR FLOW

EQUIPMENT ID. No.	
LOCATION	**Holding Area**
DATE OF QUALIFICATION	
SUPERSEDES REPORT No.	**NIL**

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR VERTICAL LAMINAR AIR FLOW	PROTOCOL No.:

REPORT CONTENTS

 PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR VERTICAL LAMINAR AIR FLOW	PROTOCOL No.:

1.0 REPORT PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- To provide documented evidence that the Equipment is performing consistently, repeatedly and reproducibly within its established operating range and the results of all the test parameters meet the pre-defined acceptance criteria.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.

3.0 SCOPE:

- The score of this report is limited for qualification of Vertical Laminar Air Flow installed in the **Holding Area**.
- This report provides all the relevant information of the performance qualification activity, In-process observations and analytical data of testing of collected samples.

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	• Initiation, Approval and Compilation of the Performance Qualification Report. • Co-ordination with Quality Control, Warehouse and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification. • Post Approval of Performance qualification report After Execution.
Production	• Review of Performance Qualification Report. • To co-ordinate and support Performance Qualification Activity. • Post Approval of Performance qualification report After Execution.
Quality Control	• Analytical Support (Microbiological Testing/Analysis)
Engineering	• Review of Performance Qualification Report for correctness, completeness and technical excellence. • Responsible for trouble shooting (if occurred during execution). • Maintenance & preventive maintenance as per schedule. • Post Approval of Performance qualification report After Execution.
External Qualification Agency (if Applicable)	• Performance of qualification activity as per Protocol.

4.1 Qualification Team:

- All the persons involved in Qualification activity detail in below table.

S.No.	NAME	DEPARTMENT	DESIGNATION	DATE & SIGN

5.0 EQUIPMENT DETAILS:

Equipment Name	Vertical Laminar Air Flow
Equipment	
Manufacturer's Name	
Model	GMP Model
Size	6" x 4 "
CFM	3000 CFM
Supplier's Name	
Location of Installation	Holding Area

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6.0 PRE – QUALIFICATION REQUIREMENTS:

Verification for availability, completeness and approval status of all the required relevant documents shall be done and observations shall be recorded in the performance qualification report.

6.1 Verification of Documents:

Record the observations for documents in the below mentioned table.

S.No.	DOCUMENT NAME	DOCUMENT / SOP No.	COMPLETED (YES/NO)	CHECKED BY (ENGINEERING) SIGN/DATE	VERIFIED BY(QA) SIGN/DATE
1.	Executed and approved Design Qualification document				
2.	Executed and approved Installation Qualification document				
3.	Executed and approved Operational Qualification document				
4.	SOP for operation & Cleaning of Laminar Air Flow				
5.	SOP for Preventive Maintenance of Laminar Air Flow				

Inference:

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Reviewed By
(Manager QA)
(Sign & Date): ……...

6.2 Training Record of Validation 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.

6.3 Calibration of Test Instruments:

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

S.No.	NAME OF TEST INSTRUMENT	DATE OF LAST CALIBRATION	NEXT DUE ON	STATUS	AVAILABILITY OF CALIBRATION CERTIFICATE	VERIFIED BY(QA) SIGN/DATE
1.						
2.						
3.						
4.						
5.						

Inference:

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Reviewed By
(Manager QA)
(Sign & Date):……...

 PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR VERTICAL LAMINAR AIR FLOW	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:

DATE	AREA/ EQUIPMENT	ID.No.	LOCATION					ACCEPTANCE CRITERIA	AVERAGE AIR VELOCITY (FT/MIN)
			1	2	3	4	5		
								The Average measured clean air velocity should be 90±20 % ft/min at 6 inches downstream from the filter face	

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

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

Inference:

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Reviewed By
Manager QA)
Sign & Date) :.....

7.2 HEPA FILTER INTEGRITY TEST (PAO TEST) REPORT

TEST INSTRUMENT DETAILS:

Instrument Name	
Make	
Calibration Date	
Calibration Due Date	
PAO upstream Concentration	

TEST RESULTS:

Date	Area/Equipment Name	HEPA Id. / S. No.	Acceptance Criteria	Observation (% of Leakage)
			The PAO penetration / leak through HEPA filters should not be greater than 0.01% of the upstream PAO concentration.	

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

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

Inference:

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Reviewed By
Manager QA)
Sign & Date) :.....

 PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR VERTICAL LAMINAR AIR FLOW	PROTOCOL No.:

7.3 DIFFERENTIAL PRESSURE RECORD

Pressure Differential	Across HEPA - Filter
Magnehelic Gauge ID No.	
Date of Calibration	
Calibration due date	
Acceptance Criteria	

Date	Name of Equipment	Observation											
		Time 00 - 04 Hr.		Time 04 - 08 Hr.		Time 08 - 12 Hr.		Time 12 - 16 Hr.		Time 16 - 20 Hr.		Time 20 - 00 Hr.	
		Time	mm of WC	Time	mm of WC	Time	mm of WC	Time	mm of WC	Time	mm of WC	Time	mm of WC

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

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

Inference:

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Reviewed By
Manager QA)
Sign & Date) :.....

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR VERTICAL LAMINAR AIR FLOW	PROTOCOL No.:

7.4 NON – VIABLE PARTICLE COUNT:

Name of Equipment	:
Particle Counter ID	
Make /Model	
Date of Calibration	
Due on Calibration	
Date of Performance Qualification	
Calibration Certificate	

Date	Area /Location	Observation				
		At Rest		Date	In operation	
		≥0.5µ	≥5.0µ		≥0.5µ	≥5.0µ

1. NMT 3,520/M^3 particles of 0.5µ or above at rest/operational Condition should be observed.

2. NMT 20/ M^3 Particles of 5.0µ or above at rest/operational condition should be observed.

Checked By:
(Production)
Sign/Date:……

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

Inference:

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Reviewed By
(Manager QA)
Sign/Date:……

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR VERTICAL LAMINAR AIR FLOW	PROTOCOL No.:

7.5 EVALUATION OF VIABLE AIRBORNE PARTICULATE TESTING (BY SETTLE PLATE)

Date of Sampling	Area Name	Sampling Location	Plate No.	Observation at 20° to 25°C For 72 Hrs (In CFU/4 Hours)	Observation at 30° to 35°C After 48 Hrs (In CFU/4 Hours)	Total Microbial Count

Acceptance Criteria: Viable air borne particle count (Settle Plate Method) for A Grade, <1 cfu/4 Hours

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

Inference:

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Reviewed By
Manager QA)
Sign & Date) :.....

7.6 EVALUATION OF VIABLE AIRBORNE PARTICULATE TESTING (BY AIR SAMPLING):

Date of Sampling	Area Name	Sampling Location	Plate No.	Observation at 20° to 25°C For 72 Hrs (In CFU/M^3)	Observation at 30° to 35°C After 48 Hrs (In CFU/M^3)	Total Microbial Count

Acceptance Criteria: Viable air borne particle count (Air Sampling Method) for A Grade, < 1 CFU/m^3

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

Inference:

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Reviewed By
Manager QA)
Sign & Date) :.....

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR VERTICAL LAMINAR AIR FLOW	PROTOCOL No.:

7.7 Recovery test:

DATE	Particulate Counts Readings At Rest						Recovery Time
	"ON"			"OFF"			
	Time	0.5 µ	5.0 µ	Time	0.5 µ	5.0 µ	
Acceptance Criteria : Recovery Time Not More Then 5 Minute							

Checked By:
(Production)
Sign/Date:……

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

Inference:

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Reviewed By
(Manager QA)
Sign/Date:……

 PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR VERTICAL LAMINAR AIR FLOW	PROTOCOL No.:

7.8 AIR FLOW PATTERN:

Date of Testing		**Make/Model**	
Instrument Name		**Calibration Date**	
Instrument ID.		**Calibration Due Date**	

Area	Air Flow Pattern Should Be Moving In Downward Direction	Visibility of Smoke Generated (Yes/No)

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

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

Inference:

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Reviewed By
Manager QA)
Sign & Date) :.....

8.0 CHECK LIST OF ALL TESTS & CHECKS

S.No.	NAME OF TEST OR CHECK	EXECUTION (YES/NO.)	REMARK	VERIFIED BY (SIGN & DATE)
1.	Air Velocity Measurement			
2.	HEPA Filter Integrity Test (PAO Test) Report			
3.	Differential Pressure Record			
4.	Non – Viable Particle Count			
5.	Recovery Test			
6.	Environmental Monitoring - (Settle Plate Method)			
7.	Environmental monitoring (Air Sampling Method)			
8.	Air Flow Pattern Test			

Inference:

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Reviewed By
(Manager QA)
(Sign & Date): .....

9.0 DOCUMENTS TO BE ATTACHED:

- Report of QC (Micro) Analysis
- Calibration Certificate of Test Instrument.
- Any Other Relevant Document

10.0 NON COMPLIANCE:

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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:

CFM	:	Cubic flow Metter
LAV	:	Vertical Laminar Air Flow
LTD.	:	Limited
mm	:	Millimetre
No.	:	Number
No.	:	Number
OQ	:	Operational Qualification
PVT	:	Private
QA	:	Quality Assurance
SOP	:	Standard Operating Procedure

17.0 REPORT POST-APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			