INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VERTICAL LAMINAR AIR FLOW

EQUIPMENT ID. No.	
LOCATION	**Liquid Filling Area (Liquid Line)**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

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

PROTOCOL CONTENTS

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

1.0 PROTOCOL PRE – APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

2.0 OBJECTIVE:

- To provide documented evidence for the Installation Qualification of Vertical Laminar Air Flow.
- To confirm that the equipment and its components are installed as per the Specifications mentioned in the design qualification document and other requirements given by supplier.

3.0 SCOPE:

- The scope of this installation qualification Protocol cum Report is limited to qualification of Bench Type Vertical Laminar Air Flow (Make: ……..) to be installed in the Liquid Filling Area.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform Installation qualification activity of Vertical Laminar Air Flow.

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, Review, Authorization and Compilation of the Installation Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Installation Qualification. • Monitoring of Installation Qualification Activity. • Post Approval of Installation Qualification Protocol cum Report after Execution.
Production	• Review & Pre Approval of Installation Qualification Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol. • Post Approval of Installation Qualification Protocol cum Report after Execution.
Engineering	• Review & Pre Approval of Installation Qualification Protocol cum Report. • Co-ordination, Execution and technical support in Vertical Laminar Air Flow Installation Qualification Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Installation Qualification Protocol cum Report after Execution

5.0 EQUIPMENT DETAILS:

Equipment Name	Vertical Laminar Air Flow
Equipment	
Manufacturer's Name	
Model	
S.No.	
Supplier's Name	Klean Air Technology
Location of Installation	Liquid Filling Area, (Liquid Line)

6.0 SYSTEM DESCRIPTION:

Vertical Laminar Air Flow in Liquid Filling Area is used to control airborne contamination of products during their extemporaneous preparation. Room air is filtered through a High Efficiency Particulate Air (HEPA) filter removing 99.999% of all particles 0.3µ or larger. Parallel air streams bathe the work area with a velocity sufficient to provide the area free of Particles and microorganisms. The direction of air flow is vertical. Laminar Air Flow are used in sterile compounding must be Class 100.

Hood does not produce sterilization, but merely prevents contaminants from settling onto the surface of the sterile product. Any movement of greater velocity and different direction than that of the hood's air flow will create a turbulence that reduces the hood's effectiveness. Contamination may be minimized by working at a smooth, steady place at least 6 inches into the hood.

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document.
- Instrumentation diagram.
- Calibration certificate of components.

7.1.1 Procedure:

- Verify the above mentioned documents for availability, completeness and approval status
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the IQ Protocol cum report.

7.1.2 Acceptance Criteria:

- All the documents should be available, complete and approved by respective authorities.

8.0 CRITICAL VARIABLES TO BE MEET:

8.1 General Checks and Location Suitability:

Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Leveling	Should be properly balanced and leveled		
Edges of parts	Metal parts should be properly grind without any sharp edges		
Welding of Joints	Welding of joints should be without any welding burrs		
Place of Installation	Filling Area		
Room Condition	General working condition		
Illumination in area	NLT 300 Lux.		
Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance		

8.2 Equipment Verification:

Installation Checks	Acceptance Criteria		Observation	Observed By (Engineering) Sign/Date
Equipment	Vertical Laminar Air Flow (Hanging Type)			
Model				
ELECTRICAL INSTALLATION:				
Electricity	Voltage	220-230 V		
	Phases	Single Phase		
	Frequency	50 Hz		
Electrical connections have been provided and secured.	Should be provided & secured			
All components in the panel are properly secured	Should be properly secured			
All terminals are tightened	Should be tightened			
Earthing connection to control panel & equipment	Earthing connection to control panel & equipment should be provided.			

8.3 Installation Checks:

S.No.	Specification	Observation	Observed By (Engineering) Sign/Date
1.	Check the proper mechanical installation of Vertical Laminar Air Flow.		
2.	Check the proper electrical installation of Vertical Laminar Air Flow.		
3.	Check the parts are working properly		
4.	Check the equipment is free from any defects		
5.	Check the finishing of product contact parts		

8.4 EQUIPMENT VERIFICATION:

S.No.	Parameters	Acceptance criteria	Observation	Observed By (Engineering) Sign/Date
1.0	**Body:**			
1.1	Make	Klean Air Technologies		
1.2	Type	Vertical Laminar Flow (Hanging Type)		
1.5	Overall dimension	3200 mm x 1550 x 300 mm		
1.6	Work area	2300 mm x 1000 mm		
1.7	MOC	SS 304		
1.8	PAO Port	01Nos.		
2.0	**Motor Blower**			
	Qty	06 Nos.		
2.1	Type	Centrifugal		
2.2	Make	M/S. Fane- Tech		

S.No.	Parameters	Acceptance criteria	Observation	Observed By (Engineering) Sign/Date
2.3	S.No	…..		
2.4	RPM	1440		
2.5	Watts	310		
2.6	Phase	Single phase		
3.0	**HEPA Filter**			
3.1	Make			
3.2	Type	Box Type		
3.3	Size	840x762x75mm-,2Nos 840x610x75mm-2Nos		
3.4	S.No.	……		
3.5	Media	Micro Glass Fiber		
3.6	Efficiency	99.999% down to 0.3µ		
4.0	**Pre Filter**			
4.1	Make	Klean Air Technlogies		
4.2	Size	675x155x100mm-4Nos		
4.3	S.No.	……..		
4.4	Type	Flange Type		
4.5	Media	HDPE+NW230+HDPE Mesh		
4.6	Efficiency	95% down to 5µ		
5.0	**LED Light**			
5.1	Size	4 feet LED Light		
5.2	Qty	02 Nos.		
5.3	Make	Drona		
5.4	Rating (Amps)	18Watts		

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

S.No.	Parameters	Acceptance criteria	Observation	Observed By (Engineering) Sign/Date
6.0	**Megnehelic gauge**			
6.1	Make	DWYER		
6.2	Range	HEPA: 0-25 mm of water. 0-10mm of water.		
7.0 Other Detail				
7.1	MOC of LAF	SS 304		
7.2	Suspension Rod	04 Nos		
7.3	PAO Port	01 Nos		
7.4	HEPA Clamp	01 Nos		
7.5	Atmosphere Nozzle	02 Nos		
7.6	Perforated Grill for	Provided		
7.7	Electrical Cable	3 mtr with Pin Top		
7.8	As Built Drawing	KAT/PC/CSVLAF/17-18/05/102		
7.9	Electrical Circuit	KAT/PC/CSVLAF/17-18/05/102		

Checked By
Production
Sign & Date:……

Verified By
Quality Assurance
Sign & Date:…….

Inference:

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Reviewed By
Manager QA
Sign/Date :.....

8.5 Safety:

Checks	Acceptance Criteria	Observation	Observed By Engineering Sign/Date
Joints	Welding of joints without any welding burrs.		
Metal Parts	All the metal parts should be properly grind without any sharp edges.		
Leveling and balancing	Equipment should be properly balanced & leveled		
Electrical wiring and earthing	Electrical wiring should be as per approved drawings. Single external Earthing to control machine (panel and motors) and operator should be provided		
Emergency Switch	Provided easy access position.		

Checked By
Production
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:

- Master Validation 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:

- Technical details for Equipment Requirement with Engineering Drawings.
- Any other relevant documents.

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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16.0 ABBREVIATIONS:

µ	:	Micron
AL	:	Aluminium
Amp.	:	Ampere
CFM	:	Cubic feet Meter
GI	:	Galvanized iron
GMP	:	Good Manufacturing practice
HEPA	:	High Efficiency Particulate Air Filter
HP	:	Horse Power
Hz	:	Hertz
IQ	:	Installation Qualification
LAV	:	Vertical Laminar Air Flow
Ltd	:	Limited
mm	:	Millimeter
MOC	:	Material of construction
No.	:	Number
P&ID	:	Piping & Instrumentation Design
SS	:	Stainless steel
V	:	Volt
WHO	:	World Health Organization

17.0 PROTOCOL POST APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			