DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR VERTICAL LAMINAR AIR FLOW

DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL CUM REPORT No.	**NIL**

PROTOCOL CONTENTS

PHARMA DEVILS	DESIGN 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 prepare the Design Qualification document for Vertical Laminar Air Flow on basis of URS and information given by Supplier.
- To ensure that all Critical Aspects of Process/Product Requirement, cGMP and Safety have been considered in designing the equipment and are properly documented.

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3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification of Bench Type Vertical Laminar Air Flow (Make: ……) to be installed in Liquid Filling Area.
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.
- The drawings provided by vendor shall be verified during Design Qualification.

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 Design Qualification Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity. • Review of Design Qualification Protocol cum Report after Execution.
Production	• Review & Approval of the Design Qualification Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Post Approval of Design Qualification Protocol cum Report after Execution.
Engineering	• Review of the Design Qualification Protocol cum Report. • Assist in the Preparation of the Design Qualification Protocol cum Report. • To co-ordinate and support the Activity. • To assist in Verification of Critical Process Parameter, Drawings as per the Specification i.e. ➢ GA Drawing ➢ Specification of the sub-components/bought out items, their Make, Model, Quantity and backup records/brochures. ➢ Details of utilities Required. ➢ Identification of components for calibration ➢ Material of construction of Product Contact Parts ➢ Brief Process Description ➢ Safety Features and Alarms • Post Approval of Design Qualification Protocol cum Report after Execution.

5.0 PROJECT REQUIRMENT:

- To confirm the safe delivery of the Equipment from the supplier Site. To ensure that no Unauthorized and / or Unrecorded design modification shall take place. If at any point in time, any change is desired in the mutually agreed design, Change Control procedure shall be followed and documented.
- The vertical LAF &, its associated components are designed in accordance with cGMP principles.

6.0 BRIEF EQUIPMENT DESCRIPTION:

The Vertical Laminar Flow Unit draws air in through the top of the unit through a pre-filter, through a plenum and vertically down over the work-surface and past the lap of the operator. It has the advantage of not pushing air into the face of the operator as in a horizontal laminar flow cabinet. The laminar air flow cabinets are used for work with low-risk substances and materials, when protection of working Material from environment is required or work with item requires a sterile working zone. Cabinets are Used for equipment of local workplaces in medical, pharmaceutical and other institutes with high Requirements for air cleanliness in the working zone.

7.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification prepared for manufacturer of equipment ensures complies with user requirement specification.

8.0 CRITICAL VARIABLES TO BE MEET:

8.1 EQUIPMENT PARAMETERS:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Application Vertical Laminar Air Flow unit is capable of delivering sufficient air volumes and to avoid the cross-contamination under the HEPA filters.	Vertical Laminar Air Flow should meet the requirement to provide a clean environment for Disinfectant Preparation Area.	Process Requirement
Working Working of VLAF	To provide a clean environment for Liquid Filling Area.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Design Requirement

8.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	Single Phase 3 Wire Line Up To The Panel Board Terminal. Voltage- 220-230 V Frequency- 50 Hz.	cGMP Requirement
Room Condition	Should be able to meet the requirement of clean environment.	Process Requirement

8.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

PARAMETERS	ACCEPTANCE CRITERIA	REFERENCE
Body:		
Manufacturer	Klean Air Technologies	Design Requirement
Type	Hanging Type Vertical Laminar Air Flow	Design Requirement
Size	10 ‘ x 3 ‘	Design Requirement
Model No.	HTVLAF-120-36	Design Requirement
Sr.No.	KAT/2017-18/87	Design Requirement
Overall Dimension	3200 mm x 1550 mm x 300 mm	Design Requirement
Work Area	2300 mm x 1000 mm	Design Requirement
Pre Filter		
Qty.	04 Nos	Design Requirement
Make	M/s.Klean Air Technologies (I) Pvt. Ltd.	Design Requirement
Size	675 x 155 x 100 mm-4 Nos.	Design Requirement
Rating	EU-6	Design Requirement
Type	Flange Type	Design Requirement
Media	HDPE+NW230+HDPE Mesh	Design Requirement
Efficiency	95% Down to 5µ	Design Requirement
M.O.C of frame	Aluminum	Design Requirement
HEPA Filter		
Qty.	04Nos	Design Requirement
Size	840 x 762x75mm-2Nos ,840x610x75mm-2Nos	Design Requirement
Make	M/s.Klean Air Technologies (I) Pvt. Ltd.	Design Requirement
Rating	EU-14	Design Requirement
Efficiency	99.999 % down to 0.3 µ	
M.O.C of frame	Aluminum	Design Requirement
Type	Box Type	Design Requirement
Motor Blower :		
Qty.	06Nos.	Design Requirement
Type	Centrifugal	Design Requirement
Make	M/s. Fane-Tech.	Design Requirement

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PARAMETERS	ACCEPTANCE CRITERIA	REFERENCE
RPM	1440	Design Requirement
Watts	310	Design Requirement
Phase	Single phase	Design Requirement
Capacity	0.40 HP (310W)	Design Requirement
LED Light		
Size	4 feet LED Light	Design Requirement
Qty.	02 Nos	Design Requirement
Make	Drona	Design Requirement
Rating(Amps.)	18Watts	Design Requirement
Pressure Gauge(Magnehelic)		
Qty.	02Nos.	Design Requirement
Type	Magnehelic Gauge	Design Requirement
Make	DWYER	Design Requirement
Range	0-25MMWC. 0-10MMWC	Design Requirement
Other Detail		
MOC of LAF	SS 304	Design Requirement
Suspension Rod	04 Nos	Design Requirement
PAO Port	01 Nos	Design Requirement
HEPA Clamp	01 Nos	Design Requirement
Atmosphere Nozzle	02 Nos	Design Requirement
Perforated Grill for Prefilter	Provided	Design Requirement
Electrical Cable	3 mtr with Pin Top	Design Requirement
As Built Drawing No.	KAT/PC/CSVLAF/17-18/05/102	Design Requirement
Electrical Circuit Drawing	KAT/PC/CSVLAF/17-18/05/102	Design Requirement

8.4 SAFETY:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Joints	Welding of joints without any welding burrs.	Safety Requirement
Metal Parts	All the metal parts should be properly grind without any sharp edges.	Safety Requirement
Leveling and balancing	Equipment should be properly balanced & leveled	Safety Requirement
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	Safety Requirement
Emergency Switch	Provided easy access position.	GMP & Safety Requirement

8.5 VENDOR SELECTION:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Selection of Vendor for supplying the Vertical Laminar Air Flow	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/financial), technical knowledge, quality standards, inspection of site, costing, feedback from market (customers already using the equipment)	Process Requirement

Checked By
Engineering
Sign & Date:……

Verified By
Quality Assurance
Sign & Date:……

Inference:

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

9.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Any other relevant documents.

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

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11.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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12.0 RECOMMENDATION:

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13.0 ABBREVIATIONS:

’	:	Feet
’’	:	Inch
µ	:	Micron
AL	:	Aluminium
CFM	:	Cubic feet Meter
cGMP	:	Current Good Manufacturing Practice
GA	:	General Arrangement
GI	:	Galvanize Iron
HEPA	:	High Efficiency Particulate Air Filter
HP	:	Horse Power
Hr	:	Hour
Hz	:	Hertz
LAV	:	Vertical Laminar Air Flow
MOC	:	Material of Construction
Sr.	:	Senior
SS	:	Stainless Steel
STD	:	Standard
URS	:	User requirement specification.
V	:	Volt
W	:	Watt

14.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY CONTROL)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			