OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR VERTICAL LAMINAR AIR FLOW

EQUIPMENT ID. No.	
LOCATION	
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL CUM REPORT No.	**NIL**

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

PROTOCOL CONTENTS

PHARMA DEVILS	OPERATIONAL 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 verify that the equipment operates in accordance with the design and user requirements as defined by set acceptance criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of Vertical Laminar Air Flow and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The scope of this operational qualification protocol cum report is limited to qualification of Vertical Laminar Air Flow (Make: …….) installed in the Disinfectant Preparation Area.
- This Protocol will define the methods and documentation used to perform OQ activity the Vertical Laminar Air Flow for OQ. Successful completion of this protocol will verify that Vertical Laminar Air Flow meet all acceptance criteria and ready for Performance 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, Approval Authorization and Compilation of the Operational Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Operational Qualification. • Monitoring of Operational Qualification Activity.
Production	• Review & Pre Approval of Operational Qualification Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol. • Post Approval of Operational Qualification Protocol cum report after Execution.
Engineering	• Review & Pre Approval of Operational Qualification Protocol cum Report. • Co-ordination, Execution and technical support in Vertical Laminar Air Flow Operational Qualification Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Operational Qualification Protocol cum report after Execution.

5.0 EQUIPMENT DETAILS:

Equipment Name	Vertical Laminar Air Flow
Equipment	……
Manufacturer's Name	Klean Air Technology
Model	
Sr.No.	
Supplier's Name	Klean Air Technology
Location of Installation	Liquid Filling Area

6.0 SYSTEM DESCRIPTION:

Vertical Laminar Air Flow in Liquid Filling Area is used to control airborne contamination of sterile 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:

- DQ Protocol Cum Report
- IQ Protocol cum Report
- SOP for operating & Cleaning of Vertical Laminar Air Flow
- SOP for Preventive Maintenance of Vertical Laminar Air Flow

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 OQ 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 MET:

8.1 Verification of documents:

S.No.	Document Name	Document/SOP No.	Checked By (Engineering) Sign/Date	Verified By QA Officer/Exe. Sign/Date
1.	DQ Protocol Cum Report			
2.	IQ Protocol Cum Report			
3.	SOP for operating & Cleaning of Vertical Laminar Air Flow.			
4.	SOP for Preventive Maintenance of Vertical Laminar Air Flow			

8.2 Test Equipment Calibration:

Equipment/ Instruments Name	Equipment/ Instrument ID	Calibration On	Due On	Observed By Sign / Date

Checked By
Production
Sign & Date:……

Verified By
Quality Assurance
Sign & Date:…….

Inference:

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

8.3 Operational and Functional Checks:

Operate the Vertical Laminar Air Flow as per Manufacturer's Manual/SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

S. No	Operation	Observation	Observed By (Engineering) Sign/Date
1.	Verify all the cabinets are properly fixed		
2.	HEPA filters & pre filter properly fixed		
3.	Grill fitment should be proper		
4.	Magnehelic gauges should start from 0 reading		
5.	All electrical (socket lights) operating		
6.	No abnormal sound is found under working condition		
7.	LED Light Glowing Properly by Switch ON		

8.4 Power Failure Verification:

Item	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Main Power shut down	Equipment stops in safe and secure condition		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions.		

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:

- Validation Master 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:

- Any Other Relevant Documents.

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:

cGMP	:	Current Good Manufacturing Practices
GMP	:	Good Manufacturing Practices
HEPA	:	High efficiency particulate air
ID.	:	Identification
IQ	:	Installation Qualification
LAV	:	Vertical Laminar Air Flow
LTD	:	Limited
No.	:	Number
OQ	:	Operational qualification
SOP	:	Standard operating procedure
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)			