OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
REVERSE LAMINAR AIR FLOW

EQUIPMENT ID. No.	
LOCATION	**PPM Sampling**
DATE OF QUALIFICATION	
SUPERSEDES No.	**NIL**

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

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

1.0 PROTOCOL PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

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 Reverse 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 **Reverse Laminar Air Flow** installed in Packing Material Sampling Area.
- This Protocol will define the methods and documentation used to perform OQ activity the Reverse Laminar Air Flow for OQ. Successful completion of this Protocol will verify that Reverse 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	• Installation, Approval and Compilation of the Operational Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Installation Qualification. • Monitoring of Operational Qualification Activity. • Review & Pre Approval of Operational Qualification Protocol cum Report.
Warehouse	• 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 Reverse Laminar Air Flow (Sampling Booth) Installation Qualification Activity. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Operational Qualification Protocol cum Report after Execution.

5.0 EQUIPMENT DETAILS:

Equipment Name	Reverse Laminar Air Flow
Equipment	
Manufacturer's Name	NA
Model	GMP
Location of Installation	PPM Sampling

6.0 SYSTEM DESCRIPTION:

Reverse Laminar Air Flow is used to perform Dispensing operations in pharmaceutical industries. The equipments serve as safety equipment to operator doing the Dispensing operation. In Dispensing from big packing of dangers chemicals converted to small packing by operator under class 100 environments and 10% exhaust system is adopted. Dispensing unit is always negative pressure unit and in equipment air is circulated from outside to inside of the equipment. Hence during Dispensing, powder is always sucked at pre filter given at the bottom of the cabinet.

Reverse Laminar Air Flow consists of HEPA Filter, Micro Filter, Pre Filter and HEPA Filter, with efficiency of 99.97% down to 0.3µ at rated air flow and pressure drop. 100 FPM is adjusted to get laminar flow in the equipment. HEPA Filter made up of imported glass fiber media as high final pressure drop for long lasting environmental clean level.

System is equipped with inbuilt motor blower dynamically balanced for low noise and vibration. Micro Filter and Pre filter at suction 10% air is discharged through exhaust HEPA Filter to generate negative pressure in equipment. To isolate the equipment, PVC curtain is used.

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

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

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:

The results of any tests should meet the limits and acceptance criteria specified in the test documents.

Any deviations or issues should be rectified and documented prior to OQ commencing.

S.No.	DOCUMENT NAME	DOCUMENT/SOP No.	COMPLETED (YES/NO)	CHECKED BY (ENGINEERING) SIGN/DATE
1.	DQ Protocol Cum Report			
2.	IQ Protocol Cum Report			
3.	SOP for operating & Cleaning of Reverse Laminar Air Flow			
4.	SOP for Preventive Maintenance of Reverse Laminar Air Flow			

Checked By
Warehouse
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date: ……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

8.2 Test Equipment Calibration:

Verify that all critical instruments associated with the system will be in a calibrated state. Review the calibration status for the test equipment to be utilised and record the calibration due dates in the table below. All Equipment/Instrumentation must remain within the calibration due date for the duration of OQ test for which the item is used. If a due date potentially occurs during the testing period then the instrument must be recalibrated before it can be utilised.

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

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

CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Blower On / Off Switch Press Switch On Position. Press Switch Off Position.	Blower Should Start. Blower Should Stop.		
Light On / Off Switch Press Switch On Position. Press Switch Off Position.	Light should get ON. Light should get OFF.		
Function of Magnehelic Gauge Starting of Magnehelic Gauge.	Needle of Magnehelic Gauge should Start from Zero.		

Checked By
Warehouse
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date: ……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

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
Warehouse
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date: ……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

9.0 REFERENCES:

- 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:

µ	:	Micron
cGMP	:	Current Good Manufacturing Practices
EQ	:	Equipment
EU	:	European Union
FPM	:	Feet Per Minute
HEPA	:	High Efficiency Particulate Air
HP	:	Horse Power
ID.	:	Identification
IQ	:	Installation Qualification
KW	:	Kilo Watt
MCB	:	Miniature Circuit Breaker
mm	:	Millimeter
MOC	:	Material of Construction
NLT	:	Not Less Than
SS	:	Stainless Steel

17.0 PROTOCOL POST -APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			