OPERATIONAL QUALIFICATION

PROTOCOL CUM REPORT

FOR

DUST COLLECTOR

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

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR DUST COLLECTOR	PROTOCOL No.:

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PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR DUST COLLECTOR	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 (PRODUCTION)			
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 Dust Collector 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, Startup & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The Protocol covers all aspects of Operation Qualification for Dust Collector.
- This Protocol cum report will define the methods and documentation used to qualify the Dust Collector for OQ. Successful completion of this Protocol cum Report will verify that the Dust Collector meet all acceptance criteria and is 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, Review, Approval and Compilation of the OQ Protocol cum Report. • Co-ordination with Production and Engineering to carryout OQ. • Monitoring of Operation Process.
Production	• Review of Operation Qualification Protocol cum Report. • To Co-ordinate and support for execution of OQ study as per Protocol. • Post Approval of Operation Qualification Protocol cum report after Execution
Engineering	• Review & Pre Approval of Operational Qualification Protocol cum Report. • Co-ordination, Execution and technical support in OQ 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	Dust Collector
Equipment ID.	
Manufacturer's Name	NA
Supplier's Name	NA
Location of Installation	Compression

6.0 EQUIPMENT DESCRIPTION:

Capture the dust with proper capture velocity from process area and send the dust collector chamber with the help of trapping Canvas Cotton Bag Filter simultaneously dust free air will go by 10 micron filter and then send to the environment.

Bag filter dust collector is efficient pollution control equipment and filtration is carried out through woven or non-woven filter media in form of bags. The cleaning action is due to high pressure air passed in the reverse direction or by providing vibration to the bags through the vibratory motor which generates the shocks to dislodge the dust particles from the bags.

S. No.	Parameter	Description
1.	**Dust Collector Details**	It comprises of: • Hose PVC Pipe for connecting with the process equipments • HDEP Pipe for connecting with the Equipment • Butter Fly Valve • AC Induction Motor • Canvas Cotton make Filter Bag • Reverse Rotating Fan • Electrical Starter Panel
2.	**Environmental conditions:** **Temperature**	Ambient (up to 30. °C)
3.	**Quantity of Air Suction**	Air Suction Velocity: 400 FPM

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

Verify that the DQ/IQ of the Dust Collector has been executed and approved. Verify that the SOP for Operation, Cleaning and Preventive Maintenance of the Dust Collector has been prepared.

S.No.	Document Name	Document / SOP No.	Completed (Yes/No)
1.	DQ Protocol Cum Report		
2.	IQ Protocol Cum Report		
3.	Draft SOP for Operation & Cleaning of Dust Collector		
4.	Draft SOP for Preventive Maintenance of Dust Collector		

Checked By **Verified By**
Sign & Date: **Sign & Date:**

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 TEST EQUIPMENT CALIBRATION:

Verify that all critical instruments associated with the system are 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.

Equipment / Instruments Name	Equipment / Instrument I.D.	Calibration On	Due On

Checked By **Verified By**
Sign & Date: **Sign & Date:**

8.2 OPERATIONAL AND FUNCTIONAL CHECKS:

Operate the Dust Collector as per Manufacturer's Manual/SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

Operational Checks	Acceptance Criteria	Observation
Power Supply		
Connect the Power Supply to the Equipment.	Door should be closed tightly & opened smoothly.	
Motor Operation		
Switch ON the Motor	Equipment should be start operating and start dust extraction.	
	After Switch ON the Motor, Reverse Rotating Fan Should move anti-clock wise direction.	
AC Induction Motor Operation for Shaking Canvas Filter Bag holder Frame		
AC Induction Motor	It should work properly and trembling the Canvas Filter Bag Holder frame for release the captured dust.	
Suction Air Velocity at Dust Collector Hose Pipe		
Suction Air Velocity (FPM)	400 FPM to 800FPM	

Checked By **Verified By**
Sign & Date: **Sign & Date:**

8.3 SAFETY TESTING:

Item	Acceptance Criteria	Observation
Motor Overload Relay or any Short Circuit	MCB should be trip if overload and any short circuit.	

Checked By **Verified By**
Sign & Date: **Sign & Date:**

8.4 POWER FAILURE VERIFICATION:

Item	Acceptance Criteria	Observation
Main Power Shut Down	Equipment stops in a safe and secure condition.	
Main Power Restored	Equipment can be restarted with no problems or adverse conditions.	

Checked By
Sign & Date:

Verified By
Sign & Date:

Inference:

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Reviewed By
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:

- Copy of Draft SOP's.
- 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:

Nos.	:	Numbers
WHO	:	World Health Organization
OQ	:	Operational Qualification
MOC	:	Material of construction
GMP	:	Good Manufacturing Practices
mm	:	Millimetre
QTY	:	Quantity
RPM	:	Revolutions per Minute
P & I	:	Piping and Instrumentation diagram
M.S	:	Mild Steel
V	:	Volts
HP	:	Horse Power
RPM	:	Revolutions per Minute
Pvt.	:	Privet
Ltd	:	Limited
AMP	:	Ampere
°C	:	Degree centigrade
CFM	:	Cubic feet Minute
MCB	:	Miniature Circuit Breaker

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 (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			