INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
DUST COLLECTOR

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

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

PROTOCOL CONTENTS

PHARMA DEVILS	INSTALLATION 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)			

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

2.0 OBJECTIVE:

- To carry out the Installation Qualification of Dust Collector used in Compression.
- To confirm that the equipment and its components are as per the Specifications and Installed as per the Approved Design and complies with GMP practices.
- To prove that each Operation proceeds as per the Design Specification and the tolerances prescribed there in the document, are the same at utmost transparency.
- To ensure that there is sufficient information available to enable the equipment to operate and Maintain safely, effectively and consistently.

3.0 SCOPE:

- To verify the critical dimensions of the unit and record Serial Numbers/Model Number of critical components.
- To verify that the correct hardware has been installed, system initializes correctly.
- To record the as-built drawing numbers of equipment drawing, P & ID and circuit diagram.

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

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

5.0 EQUIPMENT DETAILS:

Equipment Name	Dust Collector
Equipment	
Manufacturer's Name	NA
Model	GMP Model
Supplier's Name	NA
Location of Installation	Compression

6.0 SYSTEM 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 & Engineering Drawings:

- To verify that Engineering drawings and Technical details of Equipment conforms to the Design Qualification.
- To verify Certificates of MOC, Calibration of Certificates of Equipment conforms to the Design Qualification.

7.1.1 Procedure:

- Verify that Approved Engineering Drawings and Supporting Documents are available and conform to the to the DQ protocol cum Report.
- If any deviation from DQ is observed during IQ, 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:

- Drawing and documents should conform to Design Qualification cum Report. Any Deviations observed must be recorded and approved.

8.0 CRITICAL VARIABLES TO BE MET:

8.1 UTILITY REQUIREMENTS/LOCATION SUITABILITY:

Critical Variables	Acceptance Criteria	Observation
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	• Voltage: 230 V (1 Phase) / 415 V Limit +/- 10 % (3 Phase) • Phases: 1 Phase & 3 phase • Frequency: 50 Hz (+ /- 3 %)	
Area Condition	Should be able to meet the requirement as per given by the manufacturer	
Electrical Control Panel	The system should have Electrical Control Switch.	

Observed by
Sign & Date:

Checked By
Sign & Date:

8.2 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

S.No.	Parameters	Acceptance criteria	Observation
1.	**Body**	Over All Dimension in mm : 1700 x 600 x 600MM	
		MOC : MS painted sheet	
2.	**Accessories**		
	Body	Made up of MS painted sheets	
	AC Induction Motor	Qty.: 01 Nos	
	Reverse Rotating FAN	Qty.: 01 Nos	
	Butter Fly Valve at Dust Extraction Pipe	Qty.: 01 Nos	
	Control Panel for START / STOP	Qty.: 01 Nos	
	Canvas Cotton Filter Bag for Trapping the Dust	Qty.: 05 Nos	
3.	**AC Induction Motor**		
	Make	"Crompton"	
	H.P	3.0 H.P	
	RPM	2830	
	Volt	415±10%	
	AMP	5.03A	
	Frame	NA	
	S.No	….	

Checked By
Sign & Date:

Verified By
Sign & Date:

8.3 ELECTRICAL CHECKS:

S.No.	Installation Check	Observation
1.	Electrical connections have been provided and secured	
2.	All components in the panel are property secured	
3.	All terminals are tightened	
4.	Check in coming voltage/ frequency	
5.	Earthing connection to control panel & equipment	

Checked By
Sign & Date:

Verified By
Sign & Date:

8.4 SAFETY:

S.No.	Parameters	Safety / cGMP	Observation
1.	Triclover Clamp should be provided on Dust Extraction Pipe	Triclover Clamp should be provided on Dust Extraction Pipe so that entire pipe can be cleaned.	
2.	Butter Fly valve should be provided at Dust Extraction Pipe.	Butter Fly should be given for maintaining the air velocity in the pipe.	

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:

- 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:

- Technical details for Equipment Requirement with Engineering Drawings.
- Certificates of MOC
- Calibration certificates.

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
IQ	:	Installation Qualification
MOC	:	Material of construction
GMP	:	Good Manufacturing Practices
mm	:	Millimetre
QTY	:	Quantity
RPM	:	Revolutions per Minute
P & ID	:	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 Minutes

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)			