 PHARMA DEVILS	**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR DUST EXTRACTION UNIT**	**PROTOCOL No.:**

OPERATION QUALIFICATION

FOR

DUST EXTRACTION UNIT

Document Reference: IQ No.: _____

Issue Date: _____

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CONTENTS

1.0 Pre-approval Protocol:

This document has been developed and the individuals listed below have reviewed the document and agree with its content and with their signature grant approval for its execution).

Functional area	Name	Designation	Signature	Date
PREPARED BY				
User Department				
REVIEWED BY				
User Dept. Head				
Engineering Dept. Head				
Environment, health and safety				
Quality Control (if applicable)				
Quality Assurance				
APPROVED BY				
QA Head				
Plant Head				

2.0 OBJECTIVE: To ensure that the installed equipment / system operate according to the approved design, specification and manufacturers operating manual and to record all relevant information and data.

3.0 SCOPE: The scope of this Operation Qualification is for **"DUST EXTRACTION UNIT, Capacity: 180 CFM"** which is installed.

4.0 Reason for OQ:

The reason for preparing this document is:

Please tick any one (or multiple) option(s) from the following (☑):

Refurbished premises/equipment	☐	
Purchase of Utility Systems		☐
Purchase of Process Equipment	☑	
Purchase of Laboratory Equipment		☐
Bespoke or user configured computer systems	☐	
In-Use Systems that don't have a URS	☐	
Others (Specify)		☐

5.0 Refer attached Manufacturer/Supplier Operation Qualification No. (if applicable):

Refer attached OQ No.:_____.

6.0 Responsibility: Personnel involved in qualification activity.

Department	Name	Activity
User		To prepare the qualification protocol and verify all the proposed operating parameters of the equipment.
Engineering		To verify the key functionalities and equipment parameters
Health Safety and Environment		To verify the safety requirements of equipment and facility
Quality Assurance		To be a part of team and review the documents
QA Head		To review and approve the requirement and Qualification document
Plant Head		To review and approve the requirement and Qualification document

7.0 Training: Personnel involved in qualification activity.

S. No.	Name	Training status	Training report availability	Checked by/ date
7.1				
7.2				
7.3				
7.4				

8.0 VERIFICATION OF INSTRUMENTS FOR CALIBRATION:

S. No.	Instrument Name	Instrument ID	Calibration done on	Calibration due on	Checked by/ Date
8.1					
8.2					
8.3					
8.4					
8.5					
8.6					
8.7					

9.0 VERIFICATION OF STANDARD OPERATING PROCEDURE (SOP) :

Required corrections shall be carried out on draft copy of SOP and SOP shall be finalized.

S.No.	SOP Name	SOP No.	Checked by/ Date
9.1			
9.2			
9.3			

10.0 OPERATIONAL CHECK OF SOFTWARE:

S.No.	Description of test	Expectation / Acceptance criteria	Result	Pass (Yes/ No)	Checked by/ Date
10.1	NA	NA	NA	NA	NA

11.0 DETAILS OF PARAMETER OF DQ VERIFIED IN OQ:

S.No.	Parameter Mentioned in DQ	Observation in OQ	Checked by/ Date
11.1	NA	NA	NA

12.0 Functional/ Operational Requirements of Equipment:

The desired functional/ operational requirements are listed under this section.

S.No.	Operating Parameter & Test Procedure	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
Main motor functionality test				
1.	Press the green push button of the starter.	The vertex pump shall start.		
2.	Press the green push button of the starter.	The vertex pump shall stop.		
Suction test				
3.	Press the green push button of the starter.	The motor shall start and the suction pump shall start too.		
4.	Feel suction at vacuum suction nozzle at rear end of the machine using a cloth or paper.	The cloth or paper shall be seen to be sucked into the nozzle which will indicate for suction.		
5.	Press the green push button of the starter.	The motor shall stop and the suction pump shall stop too.		
Power failure and restoration				
6.	Start the machine. Trip the main incoming power supply. Wait for sometime and switch ON the main incoming power supply.	The machine shall not start until and unless it is started manually.		

S.No.	Operating Parameter & Test Procedure	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
	Main motor functionality test			
10.	**Noise level without load & with load:** A. Start the machine without any load & check the noise level with the help of dB meter. B. Start the machine with load & check the noise level with the help of dB meter.	Noise level should not be more than 90 dB		
11.	**Vibration without load & with load:** A. Start the machine without any load and check for the vibration. B. Start the machine with load and check for the vibration.	Abnormal vibrations should not be observed.		

13.0 Reference Documents: Nil.

14.0 Abbreviations: Full forms of all abbreviations are listed here.

Abbreviation		Full form
DQ	:	Design Qualification
OQ	:	Operation Qualification
SOP	:	Standard operating procedure
Dept.	:	Department
QA	:	Quality Assurance
Sr. No.	:	Serial Number
ID	:	Identification
e.g.	:	Example
&	:	And
RPM	:	Rotation per minute
HMI	:	Human machine interface

PLC : Programmable logic controller

dB : Decibel

15.0 Attachments: This section contains a list of all attachments referenced in the protocol.

S.No.	Attachment Details	Attachment No.

16.0 Deviations/ Changes (if any):

17.0 Recommendations/ Conclusion :

18.0 Post approval:

This document has been developed and the individuals listed below have reviewed the document and agree with its content and with their signature grant approval for its execution).

Functional area	Name	Designation	Signature	Date
PERFORMED BY				
User Department				
Engineering				
EHS				
Quality Control (if applicable)				
Validation QA				
REVIEWED BY				
User Dept. Head				
Quality Assurance				
APPROVED BY				
QA Head				
Plant Head				