PERFORMANCE QUALIFICATION

FOR

DUST EXTRACTION UNIT

Document Reference: OQ No.: ……..

Issue Date: _____

 PHARMA DEVILS	**PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR DUST EXTRACTION UNIT**	

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 is capable to perform consistently as intended by running the system at operational conditions and recording all relevant operation and results.

3.0 Scope: The scope of this Performance Qualification is for **"DUST EXTRACTION UNIT, Capacity: 180 CFM"** which is installed for extraction of dust from the tablet press during production and to keep the compression zone of tablet press clean.

Equipment Code: _____

4.0 Reason for PQ:

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	☐

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

Refer attached PQ No.:_____.

6.0 Responsibility: Personnel involved in qualification activity.

Department	Name	Activity
User		To prepare the performance qualification protocol and operate/ monitor/ perform the qualification activity and record.
Engineering		To provide support and perform performance qualification.
Health Safety and Environment		To verify and monitor the safety aspects.
Quality Assurance		To perform the sampling & be a part of team and review the performance of equipment and documents.
QA Head		To review and approve the Qualification document.
Plant Head		To review and approve the Qualification document.

7.0 Training: Personnel involved in performance qualification activity.

S. No.	Name	Training status	Training report availability	Checked by/ date
7.1				
7.2				
7.3				
7.4				
7.5				

8.0 ERIFICATION 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					

9.0 PERFORMANCE CHECK OR CHALLENGE STUDY OF THE EQUIPMENT:

9.1 Air volume of Dust extraction unit:

Ensure that dust extractor unit and the dust collector pipe are clean. Measure the air velocity at the suction of dust collector pipe. Calculate the air volume.

Measured Velocity (m/sec)	Dust collector pipe Internal diameter	Air volume (in CFM)	Acceptance Criteria	Checked by (Sign/ Date)
			Calculated air volume should not be less than 180 CFM.	

9.2 Back flow test of Dust extraction unit:

Start the dust extraction unit. Start compression of the batch (Product Name: _____, B. No.: _____) which result in dust generation. Stop the dust extraction unit and compression. Immediately hold a black coloured paper below the suction point. Check for any traces of powder falling down from the suction end point on the black paper.

Acceptance Criteria	Actual Result observed	Checked by (Sign/Date)
No visible powder dust should be seen at the point of use or on the black paper held below it		

10.0 PERFORMANCE CHECK OF SOFTWARE (if any):

NA

11.0 Reference Documents: Nil.

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

Abbreviation		Full form
PQ	:	Performance Qualification
No.	:	Number
QA	:	Quality Assurance
OQ	:	Operation Qualification
ID	:	Identification
SOP	:	Standard operating procedure
OOS	:	Out of specification
OOT	:	Out of trend
cGxP	:	Current good x practices, Where x stands for manufacturing, laboratory, clinical, distribution, documentation.
Sr. No.		Serial Number
m	:	Meter
Sec	:	Second
CFM	:	Cubic feet per minute

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

S.No.	Attachment Details	Attachment No.
13.1		
13.2		
13.3		
13.4		
13.5		

14.0 Deviations/ Incident/ Changes/ OOS/ OOT (if any):

15.0 Recommendations/ Conclusion :

16.0 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				