PERFORMANCE QUALIFICATION PROTOCOL FOR FILTER CLEANING MACHINE

EQUIPMENT ID No.	
LOCATION	**FILTER CLEANING AREA**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR FILTER CLEANING MACHINE	PROTOCOL No.:

PROTOCOL CONTENTS

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1.0 PROTOCOL APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER / EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

2.0 OBJECTIVE:

- To provide documented evidence that the Equipment is performing as per the parameter defined in Performance Qualification and that it gives result as per the predetermined acceptance criteria.
- To demonstrate that the system will operate reproducibly and consistently within its operating range.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.

3.0 SCOPE:

This Protocol is applicable for performance qualification of Filter Cleaning Machine installed in Filter Cleaning area.

4.0 RESPONSIBILITY:

The Qualification team, comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this Protocol.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review, and Approval of the Performance Qualification Protocol. • Co-ordination with, Production and Engineering to carryout Performance Qualification Activity. • Provide Training to qualification team.
Production	• Review of Protocol. • To co-ordinate and support Performance Qualification Activity.
Engineering	• To provide the required utility and engineering support. • Responsible for trouble shooting (if occurred during execution). • To assist the qualification team. • Maintenance & preventive maintenance as per schedule.

5.0 EQUIPMENT DETAILS:

Equipment Name	Filter Cleaning machine
Equipment ID.	
Manufacturer's Name	In House
Location of Installation	Filter cleaning area

6.0 REASON FOR QUALIFICATION:

- New equipment installed.
- After completion of the Operation Qualification of the Equipments, it is imperative to perform the Performance Qualification. The study will establish that the parameters are followed, critical variables are under control and the quality of the output is, as desired.

7.0 SITE OF STUDY:

Filter cleaning area.

8.0 FREQUENCY OF QUALIFICATION:

- Once in two year time period.
- After Change of Location.
- Major Modification in Equipment

9.0 PRE-QUALIFICATION REQUIREMENTS:

The below mentioned activities should be completed prior to commencing the performance qualification activity:

9.1 Verification of Documents:

Verification for availability, completeness and approval status of all the required relevant documents shall be done and observations shall be recorded in the performance qualification report.

- SOP for Operation & Cleaning of Filter Cleaning Machine.
- SOP for Preventive Maintenance of Filter Cleaning Machine.

9.2 Training Record of Validation Team:

- All the persons involved in the execution of Qualification Protocol must be trained in all aspects of the qualification activity including the test methodology, acceptance criteria and safety precautions to be followed during working at service floor.

10.0 TESTS & CHECKS:

10.1 Visual Inspection Test :

10.1.1 Objective:

The objective of the test to determine the Effectiveness of Cleaning of filter.

10.1.2 Scope:

The Scope of this test limited to the filter cleaning Area.

10.1.3 PROCEDURE:

10.1.3.1 The test shall be performing on Pre filter and return riser filter.

10.1.3.2 Keep the filter in filter cleaning machine horizontally by adjusting the filter stand

10.1.3.3 Close the lid of filter cleaning machine.

10.1.3.4 Now apply the raw water from the water valve (upper & lower) and set the pressure 0.5 to 2.5 kg/cm^2.

10.1.3.5 Open the compressed air valve (upper & lower) and set the pressure 0.5 to 2.5 kg/cm^2 by rotating the compressed air knob

10.1.3.6 Switch “ON” the machine & operate as per SOP.

10.1.3.7 Collect the Filter at different interval i.e. after 2 minutes, after 4 minutes and after 6 minutes and checked it visually.

10.1.3.8 Perform the three consecutive trials at different interval i.e. 2, 4, 6 minutes with different air and Water Pressure i.e. 0.5 kg/cm^2 to 2.5 kg/cm^2.

10.1.3.9 After each interval filter rinsed with the Purified water and check its cleanness visually.

10.1.4 ACCEPTANCE CRITERIA:

10.1.4.1 No dust and Product should be observed visually.

10.1.4.2 Filter should be Clean.

10.2 Verification of Cleanness by chemical analysis method:

10.2.1 Objective:

The objective of the test to determine the Effectiveness of Cleaning of filter by Chemical analysis method.

10.2.2 Scope:

The Scope of this test limited to the filter cleaning Area.

10.2.3 PROCEDURE:

10.2.3.1 The machine should be operating as per respective SOP.

10.2.3.2 Collect the Filter form the Respective area and kept into the filter cleaning machine horizontally by adjusting the filter stand.

10.2.3.3 Open the raw water supply valve (upper and lower) with 0.5 to 5.0 kg/cm^2 pressure.

10.2.3.4 Open the Compressed air Valve with 0.5 to 5.0 kg/cm^2 pressure.

10.2.3.5 Now Hold the Process for 02 minutes.

10.2.3.6 After completion of the cycle rinse with the Purified water. And collect the rinse sample and send it to QC for Chemical analysis for pH and Previous Product content.

10.2.3.7 Repeat the Process for 4 and 6 minutes as per previous point No. 10.2.3.6. And send to QC for Chemical analysis.

10.2.3.8 The Three trials shall be considered for qualification.

10.2.3.9 After receiving the analysis report from QC send the filter to Drying area.

10.2.4 Acceptance Criteria:

The previous product traces into the filter should be absent.

pH should 5-7.

11.0 CHECKLIST OF ALL TESTS & CHECKS:

The following table lists the number of tests / samples to be carried out & comments on the sample record sheet.

TESTS OR CHECKS	EXECUTED [Y/N]	COMMENT
Visual Inspection Test		
Verification Of Cleanness by Chemical analysis method		

12.0 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.

13.0 DOCUMENTS TO BE ATTACHED:

- Protocol Training record
- Chemical analysis Raw data
- Any Other Relevant Documents.

14.0 NON COMPLIANCE:

All the Non compliances of procedure, specifications, and sampling, analysis and documentation activities shall be monitored & recorded.

15.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

- In case of any deviation observed during PQ, inform to Head QA for necessary action.
- Document the deviation detail in observed deviation section.
- The Head QA shall study the impact of deviation. If deviation is acceptable and it does not have an impact on operation as well as on performance of the machine, prepare final conclusion.

16.0 CHANGE CONTROL, IF ANY:

- If any change control is required during PQ, inform to Head QA for necessary action.
- Document the details observed.
- The Head QA shall study the impact of change. If change is acceptable and it does not have an impact on operation as well as on performance of the machine, prepare final conclusion.

17.0 ABBREVIATIONS:

WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
GMP	:	Good Manufacturing Practices
FCM	:	Filter cleaning machine
PPQ	:	Performance Qualification Protocol
QA	:	Quality Assurance
SOP	:	Standard Operating Procedure
Kg	:	Kilogram
Cm^2	:	Square Centimetre
QC	:	Quality Control
PQ	:	Performance Qualification
Pvt.	:	Private
Ltd.	:	Limited