PERFORMANCE QUALIFICATION REPORT FOR FILTER CLEANING MACHINE

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

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

REPORT CONTENTS

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

1.0 REPORT PRE- 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 Report 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 Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Provide Training to qualification team.
Production	• 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). • 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 PRE-QUALIFICATION REQUIREMENTS:

6.1 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.

6.2 SYSTEM PRE-REQUISITES:

Verify that the SOP for Operating, Cleaning and Preventive Maintenance of the Filter Cleaning machine has been prepared.

S.No.	Document Name	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (QA) Sign/Date
1.	PQ Protocol approved			
2.	SOP for Operation & Cleaning of Airjet Cleaning Machine			

Checked By
Production
Sign / Date…….

Verified By
Quality Assurance
Sign/Date……..

Inference:……..……

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Reviewed By
Manager QA
Sign / Date……

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

7.0 TESTS & CHECKS:

7.1 Visual Inspection Test:

7.1.1 Trial No.: 01:

Date of Test		**Equipment ID**	
Total Filter Taken		**Type of filter**	

S.No.	Interval	Parameter			Remarks
		Water and Compressed air			
		At 0.5 kg/cm^2	At 1.5 kg/cm^2	At 2.5 kg/cm^2	
1	After 2 minutes				
2	After 4 minutes				
3	After 6 minutes				
Rejected filter (In Nos.)					

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date:……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

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

7.1.2 Trial No.: 02

Date of Test		**Equipment ID**	
Total Filter Taken		**Type of filter**	

S.No.	Interval	Parameter			Remarks
		Water and Compressed air			
		At 0.5 kg/cm^2	At 1.5 kg/cm^2	At 2.5 kg/cm^2	
1	After 2 minutes				
2	After 4 minutes				
3	After 6 minutes				
Rejected filter (In Nos.)					

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date:……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

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

7.1.3 Trial No.: 03

Date of Test		**Equipment ID**	
Total Filter Taken		**Type of filter**	

S.No.	Interval	Parameter			Remarks
		Water and Compressed air			
		At 0.5 kg/cm^2	At 1.5 kg/cm^2	At 2.5 kg/cm^2	
1	After 2 minutes				
2	After 4 minutes				
3	After 6 minutes				
Rejected filter (In Nos.)					

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date:……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

7.2 Verification of Cleanness by chemical analysis method:

7.2.1 Trial No,: 01

Date of Test		**Equipment ID**	
Sampling Time		**Type of filter**	

S. No.	Interval	Parameter						Remarks
		Water and Compressed air						
		At 0.5 kg/cm^2		At 1.5 kg/cm^2		At 2.5 kg/cm^2		
		pH	Previous Product content	pH	Previous Product content	pH	Previous Product content	
1	After 2 minutes							
2	After 4 minutes							
3	After 6 minutes							
Acceptance Criteria		The previous product traces into the filter should be absent. pH should 5-7.						

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date:……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

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

7.2.2 Trial No,: 02

Date of Test		**Equipment ID**	
Sampling Time		**Type of filter**	

S. No.	Interval	Parameter						Remarks
		Water and Compressed air						
		At 0.5 kg/cm^2		At 1.5 kg/cm^2		At 2.5 kg/cm^2		
		pH	Previous Product content	pH	Previous Product content	pH	Previous Product content	
1	After 2 minutes							
2	After 4 minutes							
3	After 6 minutes							
Acceptance Criteria		The previous product traces into the filter should be absent. pH should 5-7.						

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date:……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

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

7.2.3 Trial No,: 03

Date of Test		**Equipment ID**	
Sampling Time		**Type of filter**	

S. No.	Interval	Parameter						Remarks
		Water and Compressed air						
		At 0.5 kg/cm^2		At 1.5 kg/cm^2		At 2.5 kg/cm^2		
		pH	Previous Product content	pH	Previous Product content	pH	Previous Product content	
1	After 2 minutes							
2	After 4 minutes							
3	After 6 minutes							
Acceptance Criteria		The previous product traces into the filter should be absent. pH should 5-7.						

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date:……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

8.0 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 test by chemical analysis method		

9.0 DOCUMENTS TO BE ATTACHED:

- Protocol Training Record
- Raw Data of Chemical Analysis
- Any Other Relevant Documents

10.0 NON COMPLIANCE:

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11.0 DEVIATION FROM PRE-DEFINED 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:

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
SOP	:	Standard Operating Procedure
Kg	:	Kilogram
Cm^2	:	Square Centimetre
QC	:	Quality Control
PQ	:	Performance Qualification
Pvt.	:	Private
Ltd.	:	Limited

17.0 REPORT POST 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)			