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



PROTOCOL No.:

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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)			



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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.



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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. 			



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Sign / Date.....

5.0	EQUIPMENT	DETAILS:
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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	Verified By
Production	Quality Assurance
Sign / Date	Sign/Date
Inference:	
	Reviewed By
	Manager OA



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PHAR	MA DEVILS						
7.0	7.0 TESTS & CHECKS:						
7.1 Visual Inspection Test:							
7.1.1	Trial No.: 01:						
Date of	Test			Equipment II)		
Total F	ilter Taken	Type of filter					
				Parameter			
S.No.	Interval			nd Compressed			Remarks
		At 0.5 kg/cm ²	A	t 1.5 kg/cm ²	At 2.5 kg/cr	n ²	
1	After 2 minutes						
2	After 4 minutes						
3	After 6 minutes						
Rejecte	ed filter						
(In Nos	s.)						
Checke	•				Verified I	3y	
Produc	etion				Quality A	ssur	ance
Sign/Date:					•••••		
Inference:							
•••••							

Reviewed By Manager QA

Sign/Date:



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7.1.2	Trial No.:	02

Date of Test	Equipment ID	
Total Filter Taken	Type of filter	

C No								
S.No.	Interval	Wat	Water and Compressed air			Water and Compressed air		Remarks
		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 No	s.)							

Checked By Production Sign/Date:	Verified By Quality Assurance Sign/Date:
Inference:	
	••••••
	Reviewed By Manager QA Sign/Date:



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7.1.3	Trial No.	: U.3

Date of Test	Equipment ID	
Total Filter Taken	Type of filter	

S.No.	Interval	Water and Compressed air		Remarks	
		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				
Reject	ed filter				
(In No	s.)				

Checked By Production Sign/Date:	Verified By Quality Assurance Sign/Date:
Inference:	
	••••••
	Reviewed By Manager QA Sign/Date:



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7.2	Verification of	Cleanness	by chemical	analysis method:
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7.2.1	Trial	No.:	01

Date of Test	Equipment ID	
Sampling Time	Type of filter	

				Paramete	er			
S. No.	Interval	At 0	.5 kg/cm ²	At 1.5 kg/cm ²		At 2.5 kg/cm ²		Remarks
501100	11101 / 111		Previous		Previous		Previous	21021101211
		pН	Product	pН	Product	pН	Product	
			content		content		content	
1	After 2							
	minutes							
2	After 4							
	minutes							
3	After 6							
	minutes							
Accept	ance	The previou	s product traces in	to the filter s	hould be abs	sent.		
Criteri	a	pH should 5	-7.					

Checked By	Verified By
Production	Quality Assurance
Sign/Date:	Sign/Date:
Inference:	
	Reviewed By
	Manager QA
	Sign/Date:



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г к		 	INU.	

7.2.2 Trial No,: 02

Date of Test	Equipment ID	
Sampling Time	Type of filter	

				Paramet	er			
			Wate	er and Comp	ressed air			
S. No.	Interval	At 0	.5 kg/cm ²	At 1.5	kg/cm ²	At 2.5 kg/cm ²		Remarks
D. 110.			Previous		Previous		Previous	Tterriting
		pН	Product	pН	Product	pН	Product	
			content		content	_	content	
1	After 2							
	minutes							
2	After 4							
	minutes							
3	After 6							
	minutes							
Accept	ance	The previou	s product traces in	to the filter s	should be abs	sent.		
Criteri	a	pH should 5	-7.					

Checked By	Verified By
Production	Quality Assurance
Sign/Date:	Sign/Date:
Inference:	
	Reviewed By
	Manager QA
	Sign/Date:



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7.2.3 Trial No,: 03

Date of Test	Equipment ID	
Sampling Time	Type of filter	

				Paramete	pr				
		Water and Compressed air							
S. No.	Interval	At 0.5 kg/cm ²		At 1.5 kg/cm ²		At 2.5 kg/cm ²		Remarks	
5. 140.	intervar		Previous		Previous		Previous	Kemarks	
		pН	Product	pН	Product	pН	Product		
			content		content		content		
1	After 2								
	minutes								
2	After 4								
	minutes								
3	After 6								
	minutes								
Accept	ance	The previous product traces into the filter should be absent.							
Criteri	a	pH should 5	-7.						

Checked By	Verified By
Production	Quality Assurance
Sign/Date:	Sign/Date:
Inference:	
	•••••••••••••••••••••••••••••••••••••••
	Reviewed By
	Manager QA
	Sign/Date:



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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:
11.0	DEVIATION EDOM DE DECINED CRECIEICATION IE ANY.
11.0	DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:
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:
	••••••••••••••••••••••••••••••••
15.0	RECOMMENDATION:
	••••••••••••••••••••••••••••••••••••



PROTOCOL No.:

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

Cm² : Square Centimetre

QC : Quality Control

PQ : Performance Qualification

Pvt. : Private

Ltd. : Limited



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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)			