

PROTOCOL No.:

EQUIPMENT ID. NO.	
LOCATION	Liquid Filling Area
DATE OF QUALIFICATION	
SUPERSEDES REPORT 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 (ENGINEERING)			

# **APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			



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#### **2.0 OBJECTIVE:**

- To provide documented evidence that the Equipment is performing consistently, repeatedly and
  reproducibly within its established operating range and the results of all the test parameters meet the predefined acceptance criteria.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.

#### **3.0 SCOPE:**

- The score of this report is limited for qualification of Vertical Laminar Air Flow installed in the **Liquid** Filling Area.
- This report provides all the relevant information of the performance qualification activity, In-process observations and analytical data of testing of collected samples.



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# 4.0 **RESPONSIBILITY:**

The Validation Group, comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this Report:

DEPARTMENTS	RESPONSIBILITIES	RESPONSIBILITIES		
<b>Quality Assurance</b>	Preparation Review & Authorization and Compila	tion of the		
	Performance Qualification Report.			
	Co-ordination with Quality Control, Production and	Co-ordination with Quality Control, Production and Engineering to		
	carryout Performance Qualification Activity.	carryout Performance Qualification Activity.		
	• Monitoring of Performance Qualification.			
	• Post Approval of Performance qualification report	After Execution.		
Production	Review of Performance Qualification Report.			
	To co-ordinate and support Performance Qualification	on Activity.		
	• Post Approval of Performance qualification report	After Execution.		
<b>Quality Control</b>	Analytical Support (Microbiological Testing/Analysts)	sis)		
Engineering	Review of Performance Qualification Report for co	rrectness,		
	completeness and technical excellence.			
	Responsible for trouble shooting (if occurred during)	g execution).		
	Maintenance & preventive maintenance as per sche	dule.		
	Post Approval of Performance qualification report	After Execution.		
<b>External Qualification</b>	Performance of qualification activity as per Protoco	1.		
Agency ( if Applicable)				



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<b>Equipment Name</b>	Vertical Laminar Air Flow
Equipment	
Manufacturer's Name	
Model	
S.No.	
Supplier's Name	
<b>Location of Installation</b>	Liquid Filling Area

# **6.0 PRE – QUALIFICATION REQUIREMENTS:**

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.

#### **6.1** Verification of Documents:

Record the observations for documents in the below mentioned table.

S.No.	Document Name	Document/SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (QA) Sign/Date
1.	<b>Executed and approved Design</b>				
	Qualification document				
2.	<b>Executed and approved Installation</b>				
	Qualification document				
3.	<b>Executed and approved Operational</b>				
	Qualification document				
4.	SOP for operation & Cleaning of				
	Laminar Air Flow				
5.	SOP for Preventive Maintenance of Laminar Air Flow				

Inference:	
	Reviewed By
	(Manager QA)
	(Sign & Date):



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#### **6.2** 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.

# **6.3** Calibration of Test Instruments:

• Calibration of all the instruments used for qualification should be mentioned along with Calibration Certificates.

S. No.	Name of Test Instrument	Date of Last Calibration	Next Due on	Status	Availability of Calibration Certificate	Verified By (QA) Sign/Date
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						

	••
	••
	••
Reviewed By	
(Manager QA)	
(Sign & Date):	••



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	7.0	<b>TESTS</b>	AND	<b>CHECKS</b>
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	EDID AND CHEC								
7.1 A	IR VELOCITY M	EASUREMEN	NT:						
Instrume	ent Name								
Make									
Model / 7	Гуре								
Calibrat	ion Date								
Calibrat	ion Due Date								
Calibrat	ion Certificate Atta	ached							
OBSERV	VATION AND RE	SULTS:							
Date			A	Air Velo	city (In	Ft. /Mi	n.)	Acceptance	Average Air
	Area	Filter ID		L	OCATI	ON	Criteria	Velocity	
			1	2	3	4	5		(Ft/Min)
								The Average	
								measured clean air	
								velocity should be	
								90±20 % ft/min at	
								6 inches	
								downstream from	
								the filter face	
Checked (Enginee Sign & D	ering) Date:		1		1	1		ed By: y Assurance) z Date:	

Reviewed By
Manager QA)
Sign & Date):.....



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(Sign & Date):.....

<b>7.2</b> HEPA	FILTER INTEGRITY	TEST (PAO TEST)	REPORT	
Instrume	ent Name			
Make				
Calibration D	<b>D</b> ate			
Calibration D	<b>Due Date</b>			
Calibration C	Certificate Attached			
Up Steam Co	ncentration			
TEST RESUL	LTS:			
Date	Area Name	HEPA Id. / S. No.	Acceptance Criteria	Observation (% of Leakage)
			The PAO penetration / leak through HEPA filters should not be greater than 0.01% of the upstream PAO concentration.	
Checked By: (Engineering) Sign & Date:	)			By: Assurance) ate:
Inference:				
			Reviewed B	<b>y:</b>
			(Manager (	~



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7.3 I	DIFFERENTIA	L PRES	SURE	RECO	RD								
<b>7.3.1</b> A	Across HEPA Fi	lter:											
Pressur	e Differential						A	Across F	IEPA	- Filter			-
Magneh	nelic Gauge ID N	No.											
Date of	Calibration												
Calibra	tion due date												
Accepta	nce Criteria												
				m·		TD:		rvation		(E)		TD:	
Date Name of		Tir 00 - 04		Time 04 - 08 Hr.		Time 08 - 12 Hr.		Time 12 - 16 Hr.		Time 16 - 20 Hr.		Time 20 - 00 Hr.	
Date	Equipment	Time	mm of WC	Time	mm of WC	Time	mm of WC	Time	mm of WC	Time	mm of WC	Time	mm of WC
Checked (Engine Sign & Inference	ering) Date:	•••••							(	Verified Quality Sign & I	Assur		
									Re	eviewed	By:		

Reviewed By:
(Manager QA)
(Sign & Date):.....



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7.3.2 Across Pre Filter	.3.2	/.	Z	Across	Pre	Filtei
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cross Pre Filtei	•											
Differential				Across Pre- Filter								
elic Gauge ID N	lo.											
Calibration												
ion due date												
nce Criteria												
				10	TD:				TD:		TD:	
Name of											20 - 00	
Equipment	00 - 04	4 Hr.										
	Time	pa	Tim	e pa	Time	pa	Time	pa	Time	pa	Time	pa
l By: ring) Oate:								$(\mathbf{Q})$	uality A	ssurai		······
								(Ma	anager (	<b>QA</b> )	••••••	
	Differential  Calibration  ion due date  nce Criteria  Name of Equipment  I By: ring) oate:	Differential  Clic Gauge ID No.  Calibration  Ion due date  Ince Criteria  Name of Equipment  Time  Time  I By:  ring)  Date:	Differential  Clic Gauge ID No.  Calibration  Ion due date Ince Criteria  Name of Equipment  Time pa  Time pa  I By: I By: I ring) Date:	Differential  Plic Gauge ID No.  Calibration  Ion due date Ince Criteria  Name of Equipment  Time pa Time  Time pa Time  Time pa Time  By:  ring)  Pate:	Differential  Clic Gauge ID No.  Calibration  Ion due date  Ince Criteria   Time	Differential  Plic Gauge ID No.  Calibration  Ion due date  Ince Criteria  Time 04 - 08 08 - Hr. Hr  Time pa Time pa Time  Ime pa Time	Differential  Plic Gauge ID No.  Calibration  Ion due date  Ince Criteria     Name of Equipment   Time   04 - 08   08 - 12   Hr.     Time   pa   Time   pa   Time   pa     Time   pa   Time   pa   Time   pa     Image: Ima	Differential  Calibration  Ion due date  Ince Criteria    Name of Equipment   Time   04 - 08   Hr.   H	Differential  Di	Differential  Di	Differential  Calibration  In the paragraph of Equipment    Name of Equipment   Time   04 - 08   08 - 12   12 - 16   16 - 20	Differential   Across Pre- Filter



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# 7.4 NON – VIABLE PARTICLE COUNT

Name of equipment	:
Particle Counter Id.	:
<b>Date of Calibration</b>	:
<b>Due on Calibration</b>	:
Make	:

		Observation							
Date	Area /Location	In ope	eration	At Rest					
		≥0.5μ	≥5.0μ	≥0.5μ	≥5.0μ				

Checked By: (Engineering) Sign & Date:	Verified By: (Quality Assurance) Sign & Date:
Inference:	
	Reviewed By:
	(Manager QA)
	(Sign & Date):



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Date of Sampling	Area Name	Sampling Location	Plate No.	Observation at 20° to 25°C For 72 Hrs (In CFU/4 Hours)	Observation at 30° to 35°C After 48 Hrs (In CFU/4 Hours)	Total Microbial Count
Accentance C	<b>riteria·</b> Viah	le air horne parti	cle count (Settle F	late Method) for A	Grade <1 cfu/4 Ho	nirs
Checked By: (Engineering) Sign & Date:.	1				Verified By: (Quality Assurar Sign & Date:	nce)
Inference:						
	•••••					
				(	Reviewed By: Manager QA) Sign & Date):	



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# 7.6 EVALUATION OF VIABLE AIRBORNE PARTICULATE TESTING (BY AIR SAMPLING)

Date Of Sampling	Area Name	Sampling Location	Plate No.	Observation at 20° to 25°C For 72 Hrs (In CFU/M³)	Observation at 30° to 35°C After 48 Hrs (In CFU/M³)	Total Microbial Count
	-					
Acceptance C	 C <b>riteria:</b> Viable air b	orne particle coun	t (Air San	npling Method) for A	A Grade, < 1 CFU/	$m^3$
Checked By: (Engineering Sign & Date:					Verified By: (Quality Assurar Sign & Date:	
Inference:						
				I	Reviewed By:	
				(	Manager QA) Sign & Date):	



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/ .	/ A			<b>\                                    </b>	$\Gamma A$		<b>, I</b>	٧.

Date of Testing	Make/Model	
Instrument Name	<b>Calibration Date</b>	
Instrument ID.	Calibration Due Date	

Area	Air Flow Pattern Should Be Moving In Downward Direction	The Air Flow Pattern Shall Be From Supply Air to Return Filter	Visibility of Smoke Generated (Yes/No)

Checked By:	Verified By:
(Engineering)	(Quality Assurance)
Sign & Date:	Sign & Date:
<b>T</b> 0	
Inference:	
	Daviewed Dve
	Reviewed By:
	(Manager QA)
	(Sign & Date):



8.0	CHECK	TIST	$\mathbf{OE}$	ATT.	TESTS	<b>R</b> z	<b>CHECKS</b>
o.v	CHECK		Or.	ALL	ILOIO	œ	CHECKS

S.No.	Name of Test or Check	Execution (Veg/No.)	Remark	Verified By
		(Yes/No.)		(Sign & Date)
1.	Air Velocity Measurement			
2.	HEPA Filter Integrity Test (PAO			
	Test) Report			
3.	Differential Pressure Record			
4.	Non – Viable Particle Count			
6.	Environmental Monitoring -			
	(Settle Plate Method)			
7.	Environmental monitoring (Air			
	Sampling Method)			
8.	Air Flow Pattern Test			
Infere	nce:			
•••••			Daviewed Dve	
			Reviewed By: (Manager QA)	
			(Sign & Date)_	



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# 9.0 **DOCUMENTS TO BE ATTACHED:**

- Report of QC (Micro) Analysis
- Calibration Certificate of Test Instrument.
- Any Other Relevant Document

10.0 NO	ON COMPLIANCE:
11.0 DI	EVIATION FROM PREDEFINED SPECIFICATION IF, ANY:
••••	
12.0 CI	HANGE CONTROL, IF ANY:



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PHAR	MA DEVILS
13.0	REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):
14.0	CONCLUSION:
15.0	RECOMMENDATION:



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#### **16.0 ABBREVIATIONS:**

CFM : Cubic flow Metter

DQ : Design Qualification

IQ : Installation Qualification

LTD. : Limited

mm : Millimetre

No. : Number

OQ : Operational Qualification

PAO : Poly alpha olefin

PVT : Private

SOP : Standard Operating Procedure



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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 (ENGINEERING)			

#### **APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			