PERFORMANCE QUALIFICATION REPORT FOR DYNAMIC GARMENT CABINET

EQUIPMENT ID. No.	
LOCATION	**Entry A/L -2 MFG. Area FFS Line**
DATE OF QUALIFICATION	
SUPERSEDES REPORT No.	**NIL**

REPORT CONTENTS

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR DYNAMIC GARMENT CABINET	PROTOCOL No.:

1.0 REPORT PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

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 pre-defined 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 Dynamic garment storage cabinet installed in Entry A/L -2 for Mfg. Area of FFS Line.
- This report provides all the relevant information of the performance qualification activity, In-process observations and analytical data of testing of collected samples.

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 Protocol cum Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Initiation, Approval and Compilation of the Performance Qualification Report. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification.
Production	• Review & Pre Approval of Performance Qualification of Report. • To co-ordinate and support Performance Qualification Activity. • Post Approval of Performance Qualification report after Execution.
Quality Control	• Analytical Support (Microbiological Testing/Analysis)
Engineering	• Review & Pre Approval of Performance Qualification of Report. • for correctness, completeness and technical excellence • Responsible for trouble shooting (if occurred during execution). • Maintenance & preventive maintenance as per schedule. • Post Approval of Performance Qualification report after Execution.
External Qualification Agency (if Applicable)	• Performance of qualification activity as per protocol

4.1 Qualification Team:

- All the persons involved in Qualification activity detail in below table.

S.No.	NAME	DEPARTMENT	DESIGNATION	DATE & SIGN

5.0 EQUIPMENT DETAILS:

Equipment Name	Dynamic Garment Cabinet
Equipment	
Manufacturer's Name	Chempharm Industries India Ltd.
Model	CP-GSC-3' x 1.5' X 7'
Supplier's Name	Chempharm Industries India Ltd.
Location of Installation	Entry A/L -2 for Mfg Area FFS Line

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 (PRODUCTION) SIGN/DATE	VERIFIED BY (QA) SIGN/DATE
1.	Executed and approved Design Qualification cum report				
2.	Executed Installation Qualification cum report				
3.	Executed Operational Qualification cum report				
4.	Approved PQ Protocol				
5.	SOP for operation & Cleaning of Dynamic Garment storage cabinet				

Inference:

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

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.						

Inference:

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

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR DYNAMIC GARMENT CABINET	PROTOCOL No.:

7.0 TESTS & CHECKS:

7.1 AIR VELOCITY MEASUREMENT:

TEST INSTRUMENT DETAILS:

Instrument Name	
Make/Model	
Calibration Date	
Calibration Due Date	
Calibration Certificate Attached	
Date of Performance Qualification	

:Date	Equipment Name	Filter ID.	Air Velocity in (Ft/min) Location					Average Air Velocity (Ft/min)
			1	2	3	4	5	

Acceptance criteria:-

The Average measured clean air velocity should be 90±20% ft/min at 6 inches downstream from the filter face.

Checked By:
(Production)
Sign & Date ……...…….

Verified By:
(Quality Assurance)
Sign & Date ……...…….

Inference:

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

7.2 HEPA FILTER INTEGRITY TEST (PAO TEST) REPORT:

TEST INSTRUMENT DETAILS:

Instrument Name	
Make/Model	
Calibration Date	
Calibration Due Date	
Calibration Certificate Attached	
Date of Performance Qualification	

TEST RESULTS:

Date	Equipment 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:
(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 DYNAMIC GARMENT CABINET	PROTOCOL No.:

7.3 DIFFERENTIAL PRESSURE RECORD:

Pressure Differential	**Across HEPA - Filter**
Magnehelic Gauge ID No.	
Date of Calibration	
Calibration due date	
Acceptance Criteria	

Date	Name of Equipment	Observation											
		Time 00 - 04 Hr.		Time 04 - 08 Hr.		Time 08 - 12 Hr.		Time 12 - 16 Hr.		Time 16 - 20 Hr.		Time 20 - 00 Hr.	
		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 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 DYNAMIC GARMENT CABINET	PROTOCOL No.:

7.4 NON – VIABLE PARTICLE COUNT:

Name of Equipment	:
Particle Counter ID	
Make /Model	
Date of Calibration	
Due on Calibration	
Date of Performance Qualification	
Calibration Certificate	

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

1. NMT 3,520/M^3 particles of 0.5µ or above at rest/operational Condition should be observed.

2. NMT 20/ M^3 Particles of 5.0µ or above at rest/operational condition should be observed.

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 DYNAMIC GARMENT CABINET	PROTOCOL No.:

7.5 ENVIRONMENTAL MONITORING - (Settle Plate Method)

Date Of Sampling	Sampling Location	Area Name	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

Acceptance Criteria: Viable air borne particle count (Settle Plate Method) for A Grade, <1 cfu/4 Hours

Verified By:
(Quality Assurance)
Sign/Date:……

Inference:

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Reviewed By
(Manager QA)
Sign/Date:……

7.6 ENVIRONMENTAL MONITORING- (Air Sampling Method)

Date Of Sampling	Sampling Location	Area Name	Plate No.	Observation at 20° to 25°C For 72 Hrs (In CFU/M^3)	Observation at 30° to 35°C After 48 Hrs (In CFU/M^3)	Total Microbial Count

Acceptance Criteria: Viable air borne particle count (air Sampling Method) for A Grade, < 1 CFU/m^3

Verified By:
(Quality Assurance)
Sign/Date:……

Inference:

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Reviewed By
(Manager QA)
Sign/Date:……

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR DYNAMIC GARMENT CABINET	PROTOCOL No.:

7.7 Recovery test:

DATE	Particulate Counts Readings At Rest						Recovery Time
	"ON"			"OFF"			
	Time	0.5 µ	5.0 µ	Time	0.5 µ	5.0 µ	
Acceptance Criteria : Recovery Time Not More Then 5 Minute							

Checked By:
(Production)
Sign/Date:……

Verified By:
(Quality Assurance)
Sign/Date:……

Inference:

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Reviewed By
(Manager QA)
Sign/Date:……

7.8 AIR FLOW PATTERN TEST:

Date of Testing		**Make /Model**	
Instrument Name		**Calibration Date**	
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:
(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:

S.No.	NAME OF TEST OR CHECK	EXECUTION (YES/NO)	REMARK	VERIFIED BY (SIGN & DATE)
1.	Air Velocity Measurement			
2.	HEPA Filter Integrity Test (PAO Test) Report			
3.	Differential Pressure Record			
4.	Non – Viable Particle Count			
8.	Environmental Monitoring - (Settle Plate Method)			
9.	Environmental monitoring (Air Sampling Method)			
10.	Air Flow Pattern Test			
11.	Recovery Test			

Inference:

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Reviewed By
(Manager QA)
Sign/Date:……

9.0 DOCUMENTS TO BE ATTACHED:

- Report of QC (Micro) Analysis
- Calibration Certificate of Test Instrument
- Any Other Relevant Document
- Raw data of Performance Qualification

10.0 NON COMPLIANCE:

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11.0 DEVIATION FROM PREDEFINED 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:

%	:	Percent
&	:	And
µ	:	Micron
CFM	:	Cubic feet Meter
CFU	:	Colony forming unit
EU	:	European union
ft^3	:	Cubic feet
GMP	:	Good Manufacturing practice
HEPA	:	High Efficiency Particulate Air Filter
IB	:	Injection block
ID.	:	Identification
ISO	:	Indian standard of organization
Ltd	:	Limited
m^3	:	meter cube
mg	:	micro gram
min	:	Minute
mm	:	Millimeter
No.	:	Number
PAO	:	Poly alpha olefin
PPQ	:	Protocol performance qualification
Pvt.	:	Private
QA	:	Quality Assurance
SCA	:	Soyabean casein agar
SOP	:	Standard operating procedure
SSG	:	Sterile storage cabinet
WFI	:	Water for injection
WHO	:	World Health Organization

17.0 REPORT POST-APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			