PERFORMANCE QUALIFICATION

PROTOCOL

FOR

DYNAMIC GARMENT CABINET

EQUIPMENT ID. No.	
LOCATION	**Entry A/L -2 for Mfg Area, FFS Line**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

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

PROTOCOL CONTENTS

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

1.0 PROTOCOL 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 the Entry A/L -2 for Mfg Area Ground Floor 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 of the Performance Qualification Protocol. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification Activity as Per protocol.
Production	• Review & Pre Approval of Performance Qualification protocol to co-ordinate and support Performance Qualification Activity.
Quality Control	• Analytical Support (Microbiological Testing/Analysis)
Engineering	• Review & Pre Approval of Performance Qualification protocol for correctness, completeness and technical excellence • Responsible for trouble shooting (if occurred during execution). • Maintenance & preventive maintenance as per schedule.
External Party (If Applicable)	• Performance Qualification 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 SYSTEM DESCRIPTION:

Dynamic Garment Storage Cabinet is used to maintain Class 100 through HEPA filter having an efficiency of 99.99% down to 0.3µ, with a velocity of 90±20% fpm, at its face to remove dust and atmosphere contaminants from air and maintain Garments in Class 100 environment.

Dynamic Garment Storage Cabinet consists of HEPA filters with an efficiency of 99.99% down to 0.3µ with permitted pressure drop. The system is equipped with a motor blower assembly and Pre-filter to suck air from atmosphere and to pass it through HEPA filter.

7.0 REASON FOR QUALIFICATION:

- New equipment in Entry A/L -2 for Mfg Area Ground Floor, FFS Line**.**
- 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.

8.0 SITE OF STUDY:

Entry A/L -2 for Mfg Area Ground Floor, FFS Line**.**

9.0 FREQUENCY OF QUALIFICATION:

S.No.	TESTS	PERFORMANCE QUALIFICATION FREQUENCY
1.	**Air Velocity Measurement**	• Initially • Once in a 6 months
2.	**Filter Integrity Test (PAO test)**	• Initially • Once in a year
3.	**Differential pressure record**	• Daily for 3 days at every 4 hrs. interval.
4.	**Non-Viable Particle count**	• Initially • Once in 6 months
5.	**Viable Particulate Count Test(Passive & Active Air Sampling)**	• Settle plate -7 days • Air sampling - 7 days
6.	**Air Flow Pattern Test**	• Initially • Once in 2 year
7.	**Recovery Test**	• Initially (Additional Test)

10.0 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.

10.1 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 document				
2.	Executed and approved Installation Qualification document				
3.	Executed and approved Operational Qualification document				
4.	SOP for operation & Cleaning of Dynamic garment Cabinet				

10.2 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.

10.3 Calibration of Test Instruments:

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

11.0 TESTS AND CHECKS:

11.1 EVALUATION OF AIR VELOCITY:

11.1.1 Objective:

- To verify the Average Air Flow Velocity across the HEPA filter in Dynamic Garment Storage Cabinet.

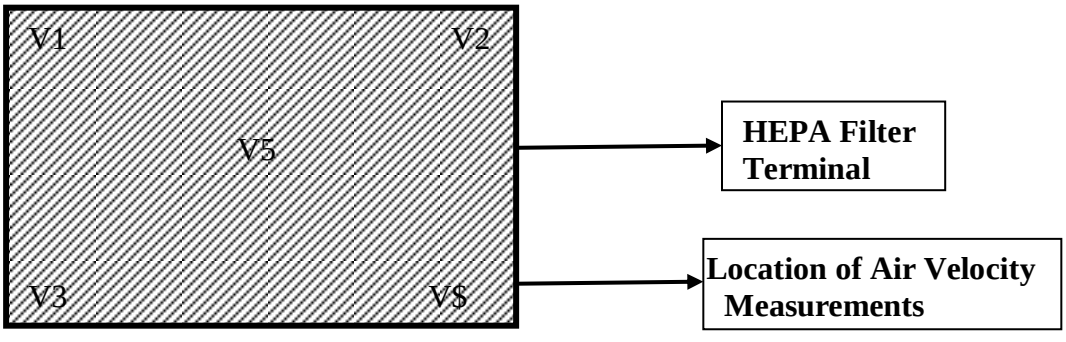
11.1.2 Equipment and Instruments

- Vane type Anemometer/Pitot Tube and Manometer/Hot wire anemometer

11.1.3 Procedure:

- Measure airflow velocities at the four corners and center of filter about 6 inches downstream of the filter.
- Measurement time at each location should be at least 10-second duration and the values should be recorded.

Sampling point on the filter.



- Define the measuring plane and measuring point shall be defined at a distance between 150 mm and 300 mm from face of filter (Supply Source).

11.1.4 Acceptance Criteria:

- An air flow rate of 90 ± 20 % feet per minute shall be maintained and measured at 6 inches below HEPA's.

11.1.5 Observation:

- Record the observations in the performance qualification report.

11.2 HEPA FILTER INTEGRITY TEST:

11.2.1 Objective :

- To demonstrate that HEPA Filter is capable of filtering above the 0.3 µ size particle.

11.2.2 Equipments & Instruments:

- Aerosol photometer and scanning port.

11.2.3 Procedure:

- Before starting the test start the Dynamic Garment Storage Cabinet before one hour.
- Check PAO (Poly Alfa Olefin) solution level into aerosol photometer tank,
- Position the aerosol generator and introduce Aerosol into the upstream air, ahead of HEPA filters .at the concentration of 80-100 mg/liter of air at the filters designed airflow rating.
- Set the instrument at 100% concentration.
- Connect the compressed air to aerosol photometer.
- Orient the supply tube (PU tube) of aerosol toward the grill and orient the PU tube (for Down stream Concentration) on opening of supply aerosol tube - than check the upstream Concentration 100 % above the HEPA through port.
- Keep the aerosol supply tube near the grill.
- Scan the Supply grill (HEPA Grill) for checking filter integrity test at a sampling rate of $1ft^3$/min.
- The probe should scan the filter face and frame at a position about 1to2 inches from the face of the filter.
- Scanning shall be done at a rate of maximum 2 feet per minute

11.2.4 Acceptance criteria:

- During scanning percentage of the PAO penetration shown by photometer should be less than 0.01% through the filter media and should be zero through mounting joints.

11.2.5 Observation:

- Record the observations in the performance qualification report.

11.3 DIFFERENTIAL PRESSURE ACROSS HEPA FILTER:

11.3.1 Objective:

- To demonstrate that the air system is capable to delivering sufficient air volume and maintain Pressure Differential across the pre-filter & HEPA Filter in Laminar Air Flow.

11.3.2 Equipment and Instrument:

- Calibrated Magnehelic Gauge.

11.3.3 Procedure:

- Operate the **Dynamic Garment Storage Cabinet** about 15 mins. prior to recording the Differential Pressure Across HEPA.
- Measure and record the Differential Pressure at every 4 hrs interval for up to 3 days.

11.3.4 Acceptance Criteria:

- Differential pressure across the HEPA Filter should be in the range of (10-20 mm of water).

11.3.5 Observation:

- Record the observations in performance qualification report in.

11.4 NON -VIABLE PARTICULATE COUNT TEST:

11.4.1 Objective:

- To demonstrate that the critical work locations/ stations within the clean rooms comply with their designed conditions and/or the cleanliness class with respect to the level of Non viable particle count and are in line with the regulatory requirements.

11.4.2 Equipment & Instruments: Particle counter

11.4.3 Procedure:

- Set particle counter at designated sampling location, & collect 1000 L. of air to evaluate the particles of 0.5µ & 5.0 µ from the sampling location.

11.4.4 Acceptance Criteria:

AIRBORNE PARTICULATE CLASSIFICATION FOR MANUFACTURE OF STERILE PRODUCTS

S. No.	Maximum number of permitted particles per cubic metre equal to or above as tabulated.	
	Particle size	Acceptance criteria
1	≥ 0.5 µ Particle	NMT 3,520 particles / M^3 of 0.5µ or above at rest /Operational condition should be observed.
2	≥ 5.0 µ Particle	NMT 20 / M^3 Particles of 5.0µ or above at rest /in operation condition should be observed

11.4.5 Observation:

- Record the observations in the performance qualification report

11.5 RECOVERY TIME TEST:

11.5.1 Objective:

- This test is performed to determine the ability of the installation to eliminate airborne particles.

11.5.2 Equipment and Instrument:

- Calibrated Particle counter

11.5.3 Procedure

- Take initial reading while Dynamic Garment Storage Cabinet is on.

- Now off Dynamic Garment Storage Cabinet and take reading till particle count crosses limit for either 0.5µ &5µ particles or then restart Dynamic Garment Storage Cabinet till particle count for both 0.5µ &5µ come again within limit.
- Now take difference from Dynamic Garment Storage Cabinet restart time and to the time when the count for 0.5µ &5µ particles comes again within limit

1.1.1 Acceptance Criteria:

- Recovery period should not be more than 05 minutes.

1.1.2 Observation:

- Record the observations performance qualification report.

11.6 VIABLE AIR BORNE PARTICULATE COUNT TEST (By Settle Plate & Air Sampler):

11.6.1 Objective:

- To demonstrate that the critical work locations/stations within the clean rooms comply with their designed conditions and/or the cleanliness class with respect to the level of microbial contamination and are in line with the regulatory requirements.

11.6.2 Procedure For Settle Plate Method:

- Prepare the media plates with Soyabean casein digest agar (SCDA).
- Expose the plates in the areas at different locations for NMT 4 hours.
  Incubate the exposed plates at 22.5 ± 2.5ºC for 72 hours initially followed by at 32.5ºC ±2.5ºC for 48 hours.
- Examine the plates visually after above mentioned period for any fungal and bacterial growth.
- Enter the results in the microbial test report.

11.6.3 Procedure For Air Sampling Method:

- Sanitize the air sampler with filtered 70% IPA.
- Transfer the air sampler in to concern area pass box and again sanitize with filtered 70% IPA.
- At the sampling location open the top lid of pre incubated SCA plate and keeps the plate in cone of air sampler.
- After that immediately remove the aluminum foil or butter paper of perforated sieve and set it with head of air sampler over the SCA plate. Vertically put the air sampler at the sampling location and carry out the air sampling of 1000 ltr.

- After air sampling, remove the plate (in the same area where it is exposed) from air sampler, close the lid immediately and place aside. Immediately clean the head cone of air sampler with lint free cloth previously wetted with filtered 70% IPA and carry out the air sampling for other specified locations.
- After air sampling collect, all the plates and wrap with same single aluminum foil. Place the plates in SS container and bring back the sampled plates in microbiology lab for incubation.
- Incubate all the plates first at 22.5 ± 2.5°C for 72 hours and then at 32.5°C ±2.5°C for 48 hours in inverted position. For negative control incubate SCA plate as it is without streaking.

11.6.4 Acceptance Criteria:

- Performance Qualification shall be considered acceptable when all the conditions specified in Various annexure have been met.
- Any deviation from the acceptance criteria of the specific check point shall be reported and decision should be taken for the rejection, replacement or rectification of the equipment component.

Acceptance Criteria for viable air borne particle count
as per (EU Guide to Good Manufacturing Practice, Part 4, 1997)

Grade	Recommended limits for microbial contamination.	
	Air Sample CFU/m^3	Settle plate (Diameter 90 mm) CFU/4 Hours
A	<1	<1

11.6.5 Observation:

- Record the observations in performance qualification report in

11.7 AIR FLOW PATTERN TEST

11.7.1 Objective:

- The purpose of airflow direction test and visualization is to confirm that the airflow direction and its uniformity confirm to the design specifications.

11.7.2 Equipment Used:

- Video Camera & Aerosol Generator by Glycol base /Fogger/WFI or Distilled water

11.7.3 Procedure:

- Generate the aerosol with the help of Generator in the desired area where air flow direction test is being conduct.
- Supply of aerosol generator pipe should be placed typically 12 to 24 inches away from the HEPA filter face in downward position.
- After placing downward position, start the smoke remotely from the source and simultaneously shoot the video.
- Move the smoke generator pipe through the entire area to be tested, sliding the hands free stand slowly so that the whole clean zone area is observed and video recorded.

11.7.4 Acceptance Criteria:

- Airflow direction should be moving in a downward direction

11.7.5 Observation:

- Record the observations in performance qualification report

12.0 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			
5.	Recovery Test for particle count.			
6.	Environmental Monitoring - (Settle Plate Method)			
7.	Environmental monitoring (Air Sampling Method)			
8.	Air Flow Pattern Test			

13.0 REFERENCES:

The Principle Reference is the following:

- Validation Master Plan
- Schedule-M – "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."
- EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use Annex -1 Manufacture of Sterile Medicinal Products.- February 2008
- ISO 14644 of Clean Rooms and Associated Controlled Environments..

14.0 DOCUMENTS TO BE ATTACHED:

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

15.0 NON COMPLIANCE:

- In case of any Non-Compliance observed during performance test, inform to head QA for required action.
- All the required action should be addressed in the report and justified.

16.0 DEVIATION FROM PREDEFINED 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 will study the impact of deviation. If deviation is acceptable and it does not have an Impact on properties of product & prepare final conclusion.

17.0 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 will study the impact of change. If change is acceptable and it does not have an Impact on properties of product & prepare final conclusion.

18.0 ABBREVIATIONS:

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