PERFORMANCE QUALIFICATION PROTOCOL FOR DYNAMIC PASS BOX

EQUIPMENT ID. NO.	
LOCATION	**External Corridor to Washing & Sterilization Area**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL NO.	**NIL**

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR DYNAMIC PASS BOX	PROTOCOL No.:

PROTOCOL CONTENTS

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR DYNAMIC PASS BOX	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 protocol is limited for performance qualification of Dynamic pass box installed Between **External Corridor to Washing & Sterilization Area**
- This protocol 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:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Initiation, Approval of Performance Qualification Protocol. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification.
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 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 Pass Box
Equipment	
Manufacturer's Name	
Model	CP- DPB-2'x2' x2'
Supplier's Name	
Location of Installation	External corridor to Washing & Sterilization Area

6.0 SYSTEM DESCRIPTION:

Dynamic pass box is installed between two rooms, of different class. Through which the materials are transferred from one room to another to protect the interference and is equipped with interlocking system. Only one door can be opened at a time. The door will get inter-locked.

The system is equipped with UV, sandwich doors with viewing window, and timer and interlocking between the doors. Pass box will act as a barrier between different class area to maintain the integrity of the area.

Switch ON the main switch & switch ON the UV light 20 minutes before starting the works.

To open the door gently turns the round handle to right and to close press the door smoothly inside so that the door will be locked.

7.0 REASON FOR QUALIFICATION:

- New equipment installed in External Corridor to Washing & Sterilization Room.
- 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:

- Dynamic pass box installed in External Corridor to Washing & Sterilization Room.

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**	• 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 (ENGINEERING) SIGN/DATE	VERIFIED BY(QA) SIGN/DATE
1.	Executed and approved Design Qualification cum report				
2.	Executed and approved Installation Qualification cum report				
3.	Executed and approved Operational Qualification cum report				
4.	SOP for operation & Cleaning of Dynamic pass box				
5.	SOP for operation & Cleaning of Dynamic pass box				

Inference:

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

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:

The following performance test have been carried out in order to demonstrate the Performance in Conformance

11.1 EVALUATION OF AIR VELOCITY:

11.1.1 Objective:

- To verify the Average Air Flow Velocity across the HEPA filter in Dynamic pass box.

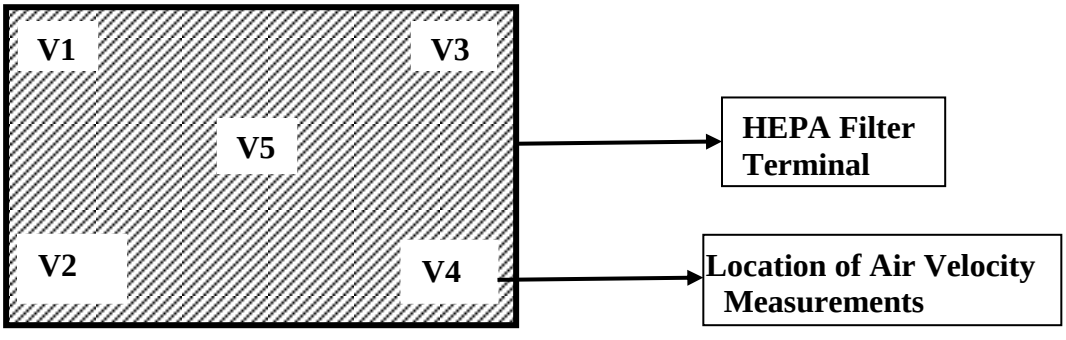
11.1.2 Equipment and Instruments

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

11.1.3 Procedure:

- Measure airflow velocities at the four corners and center of HEPA 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.



11.1.4 Acceptance Criteria:

- Air flow Average 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 pass box 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.

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 HEPA Filter in Dynamic pass box.

11.3.2 Equipment and Instrument:

- Calibrated Magnehelic Gauge.

11.3.3 Procedure:

- Operate the Dynamic pass box system about 15 minute. prior to recording the Differential Pressure.
- 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 in Dynamic pass box shall be in the range of (10-20 mm of Water)

11.3.5 Observation:

- Record the observations in performance qualification report.

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. air to evaluate the particles of 0.5µ & 5.0 µ from the sampling location.
- Non Viable Particle Count Performed at Rest & Operational Condition

11.4.4 Acceptance Criteria:

AIRBORNE PARTICULATE CLASSIFICATION FOR MANUFACTURE OF STERILE PRODUCTS

S.No.	Maximum number of permitted particles per cubic meter.	
	Particle size	**Acceptance criteria**
1	≥ 0.5 µ Particle	NMT 3,520 particles / M^3 of 0.5µ at rest/in operation condition should be observed in Grade- A
2	≥ 5.0 µ Particle	NMT 20 / M^3 Particles of 5.0µ at rest /in operation condition should be observed in Grade-A

11.4.5 Observation:

- Record the observations in the performance qualification report

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

11.5.1 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.

11.5.2 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 ± 2.5°C for 72 hours initially followed by at 32.5°C ±2.5°C 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.

11.5.3 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 SCDA 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 SCDA plate. Vertically put the air sampler at the sampling location and carry out the air sampling of 1000 L.

- 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^{o}C for 72 hours and then at 32.5^{o}C ±2.5^{o}C for 48 hours in inverted position. For negative control Incubate SCDA plate as it is without streaking.

11.5.4 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.

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

11.5.5 Observation:

- Record the observations in performance qualification report.

11.6 AIR FLOW PATTERN TEST

11.6.1 Objective:

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

11.6.2 Equipment Used:

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

11.6.3 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 6 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.

11.6.4 Acceptance Criteria:

- Airflow direction should be moving in a downward direction

11.6.5 Observation:

- Record the observations in performance qualification report.

11.7 RECOVERY TIME TEST:

11.7.1 Objective:

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

11.7.2 Equipment and Instrument:

Calibrated Particle counter

11.7.3 Acceptance Criteria:

Recovery period should not be more than 05 minutes

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			
6.	Environmental Monitoring (Settle Plate Method)			
7.	Environmental monitoring (Air Sampling Method)			
8.	Air Flow Pattern Test			
9.	Recovery Test			

Inference:

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

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."
- WHO Technical Report Series 961, Annexure - 05.
- EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use Annex -1 Manufacture of Sterile Medicinal Products.- February 2008
- ISO 14644-1 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

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:

%	:	Percent
&	:	And
<	:	Less Then
µ	:	Micron
µg	:	micro gram
CFM	:	Cubic feet Meter
CFU	:	Colony forming unit
DYP	:	Dynamic pass box
EU	:	European union
ft^3	:	Cubic feet
GMP	:	Good Manufacturing practice
HEPA	:	High Efficiency Particulate Air Filter
ISO	:	International standard of organization
LTD	:	Limited
m^3	:	meter cube
min	:	Minute
mm	:	Millimeter
No.	:	Number
PAO	:	Poly alpha olefin
SCDA	:	Soybeans casein Digest agar
SOP	:	Standard operating procedure
WFI	:	Water for injection
WHO	:	World Health Organization