PROTOCOL

FOR

QUALIFICATION

OF

DYNAMIC PASS BOX

EQUIPMENT ID NO.:……..

AREA: MICROBIOLOGY LAB (QA/QC BLOCK)

LOCATION:……

Protocol No.	
Supersedes Document Number	
Effective Date	
No. of Pages	**32**

1.0 PROTOCOL APPROVAL

This is a specific protocol for Qualification of Dynamic Pass Box (Equipment ID No.: …….) which is installed, in Microbiology Lab (QA/QC Block).

This protocol has been prepared, checked and approved by the following:

INITIAL APPROVAL

This protocol has been approved by the following:

PREPARED BY:

Name	Designation	Department	Signature	Date
		QC Microbiology		

CHECKED BY:

Name	Designation	Department	Signature	Date

FINAL APPROVAL:

Name	Designation	Department	Signature	Date

2.0 OVERVIEW:

2.1 OBJECTIVE:

To establish the methodology for the Performance qualification of Dynamic Pass Box (Equipment ID No.:……..) which is kept in Microbiology lab (QA/QC Block) of ……..

2.2 PURPOSE AND SCOPE:

The purpose of this protocol is to establish documentary evidence that Dynamic Pass Box (Equipment ID No.:…….) should be qualified to maintain class 5 as per ISO 14644-1 standard within the working area for performing microbiological testing.

This protocol is applicable for the Performance Qualification of the Dynamic Pass Box (Equipment ID No.:……) which is kept in Microbiology lab (QA/QC Block) of ……..

2.3 RESPONSIBILITY:

- **Protocol/Report Preparation:** Executive Microbiology
- **Protocol/Report checking:** Manager QC/Manager QA
- **Approval of Protocol/Report:** Head QA
- **Execution of Qualification Activity:** Executive Microbiology

2.4 QUALIFICATION TEAM:

- Microbiologists/Executive Microbiology
- Quality Assurance Executive/Manager

3.0 TRAINING RECORD:

3.1 PURPOSE:

The purpose of the training is to familiarize the trainees with the overall strategy of Qualification of Dynamic Pass Box (Equipment No.:……..).

3.2 SCOPE:

This Training is applicable to the Qualification of Dynamic Pass Box (Equipment ID No.: …….).

3.3 TOPICS:

The following topics shall be covered during training:

- Overall strategy of qualification process.
- General precautions / guidelines to be followed during qualification.
- **Training records shall be attached with the report as Annexure – 01.**

4.0 QUALIFICATION REQUIREMENTS:

Following instruments shall be required for the Qualification of Dynamic Pass Box (Equipment ID No.:.....).

S.No.	Instrument Name	Instrument Code / Sr. No.	Calibration Certificate No.	Calibration Due On
1.	Differential Pressure Gauge			
2.	Anemometer			
3.	Laser Particle Counter			
4.	Photometer			

Calibration Certificates shall be attached as **Annexure-04**.

5.0 SYSTEM / EQUIPMENT DESCRIPTION

5.1 SYSTEM / EQUIPMENT DETAILS

The Dynamic Pass Box (Equipment ID No.:.....) shall be used to transfer the material from sterility lab to MLT/BET lab and samples and other testing aids from non-sterile area to sterility lab.

5.2 SYSTEM /EQUIPMENT IDENTIFICATION

Component	Specifications
Name of equipment	Dynamic Pass Box
Model	
Serial Number	
Tag No.	
Name of the Manufacturer	
Overall Dimensions	830 x 690 x 1390 mm

Working Area	610 x 610 x 610 mm
HEPA filter	610 x 610 x 69 mm -01 No.
Pre-Filter	275 x 325 x 50 mm -01 No.
UV Lamp	Philips 15 watt
Hour meter	Make-..... 01No.
Details of Purchase Order No.	.....
Equipment Location	Microbiology laboratory (QA/QC Block)

6.0 QUALIFICATION PROCEDURE:

The following procedure shall be used for the Qualification of the Dynamic Pass Box (Equipment ID No.:.....).

Tests to be performed by out side party:

- ♦ Differential Pressure
- ♦ Air velocity
- ♦ Non viable air borne particle count
- ♦ Filter Leakage test (HEPA filter Integrity test)
- ♦ Air Flow Patterns
- ♦ Air viable count by active air sampling (Using Air Sampler)
- ♦ Passive Air Sampling (Settle Plate Method)
- ♦ Surface Monitoring by Contact plate method
- ♦ Recovery Study

6.1 DIFFERENTIAL PRESSURE:

OBJECTIVE:

To demonstrate the capability of the Dynamic pass box to provide pressure gradient between working area and surroundings.

PROCEDURE:

6.1.1 Differential pressure shall be monitored from the calibrated magnehelic gauge for three consecutive days.

6.1.2 Dynamic pass box shall be continuous operation while taking observations.

ACCEPTANCE CRITERIA: 10-15 mm of WC (Water Column).

Observations shall be recorded as per **Exhibit-05.**

6.2 AIR VELOCITY:

OBJECTIVE:

To demonstrate that the air system is balanced and capable of delivering air velocity so that air flow remains in Laminar Fashion.

PROCEDURE:

6.2.1 Air velocity shall be recorded using calibrated digital Anemometer.

6.2.2 Anemometer shall be kept at the distance of approximately 6 inches from the grill of HEPA filter.

6.2.3 Five reading shall be taken from the locations as shown in the fig. V1, V2, V3, V4, AND V5. Record the Air velocity at five locations V1, V2, V3, V4 and V5.

6.2.4 Average velocity (V) in FPM shall be calculated as follows:

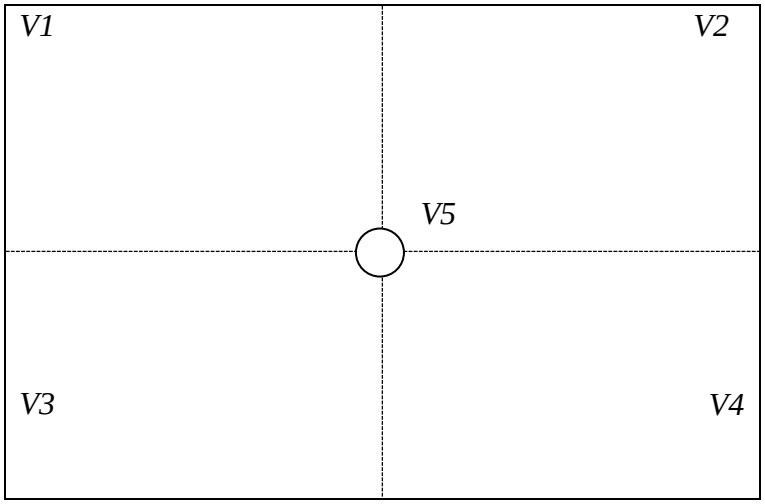
$$V = \frac{\sum Vi}{5}$$

Where i is the location 1 to 5 and Vi is the velocity at location 1 to 5.

6.2.5 The observations of Air velocity shall be recorded as per **Exhibit-E01.**

ACCEPTANCE CRITERIA: The average velocity shall be within 90 ± 20 % Feet per minute.

Diagram showing Hypothetical division of HEPA grill



6.3 NON -VIABLE AIR BORNE PARTICLE COUNT TEST:

OBJECTIVE:

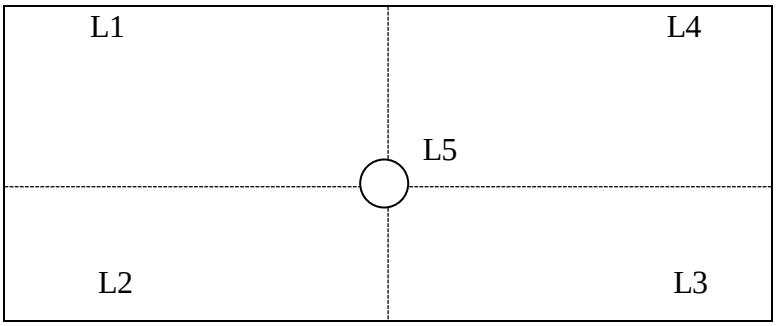
To establish that Dynamic Pass Box working area meets the requirement for cleanliness Class 5 as per ISO 14644-1 standard.

PROCEDURE:

6.3.1 After moping the Dynamic Pass Box with 70% IPA let the air flow for 30 minutes prior to perform this test and the particle count shall be done at rest conditions.

6.3.2 Record the particle count greater than 0.5µ and 5.0 µ size at 5 different locations as shown in the diagram given below.

Diagram showing locations of air sampling for nonviable particle count



6.3.3 The minimum volume to be sampled shall be calculated by the following equation:

$V_s = (20 / C_{n,m}) \times 1000$

Where: V_s is the minimum sample volume, in litres

$C_{n,m}$ is the class limit (in number of particles per cubic meter for a given particle size)

6.3.4 The minimum sample time at each location must be 1 minute and the minimum volume of air sampled at each location shall be 2 Liters.

6.3.5 Count the number of particles using Laser Particle Counter.

6.3.6 Three readings shall be taken at each location.

6.3.7 **Mean of** averages**, M** = $(A_1+A_2 + \text{-----} + A_n) / n$

Where A_1, A_2 are the average of three reading taken at each location.

ACCEPTANCE CRITERIA: The number of particles shall not increase more than the limit Mentioned in the table below.

Class	**Maximum permitted no of particles / m^3 of air**	
	≥0.5µ	**≥5.0µ**
	Particles /m^3	**Particles /m^3**
100	**3520**	**29**

6.3.8 The observations of nonviable particle count shall be recorded as per **Exhibit-E02.**

6.4 FILTER LEAKAGE TEST (HEPA FILTER INTEGRITY TEST):

OBJECTIVE:

Filter leak test shall be checked in order to find out that HEPA filter are not damaged and there is no leakage from the filter media joints and frames etc.

PROCEDURE:

6.4.1 Filter integrity testing shall be checked using PAO (Poly-alpha olefin) smoke generator Aerosol photometer.

6.4.2 Position the smoke generator and introduce PAO smoke into the upstream air through port at the concentration of 20 mg/m^3 (µg/l) and 80 mg/m^3 (µg/l).

6.4.3 Hold the probe in front of HEPA filter grill, switch ON the photometer and allow stabilizing.

6.4.4 Move the probe along the joints slowly.

6.4.5 Record the observation as per **Exhibit-E03.**

ACCEPTANCE CRITERIA:

Not more than 0.01% PAO shall penetrate across the HEPA filter and no leakage shall be observed from the fitment.

6.5 AIR FLOW PATTERNS:

OBJECTIVE:

To demonstrate that the air pressure is balanced and air is flowing from high pressure zone to low pressure zone and uniform laminar flow. The test shall be performed to check the air flow patterns in the Dynamic pass box using TiCl4.

PROCEDURE:

6.5.1 Take a glass rod.

6.5.2 Dip it in TiCl4 and keep in front of air flow of the running Dynamic pass box.

6.5.3 Pattern of air flow shall be recorded by video camera.

6.5.4 The observations shall be recorded as per **Exhibit-E09.**

6.5.5 CD shall be enclosed along with the report as **Annexure-03.**

6.5.6 The observations shall be recorded as per **Exhibit-09**.

ACCEPTANCE CRITERIA:

The air flow patterns shall be in vertical direction in a laminar fashion.

6.6 AIR VIABLE COUNT BY ACTIVE AIR SAMPLING:

6.6.1 Sanitize the Dynamic pass box with 70% v/v Isopropyl alcohol properly.

6.6.2 Switch ON the UV lamp for 15 minutes. Switch ON the air flow also.

6.6.3 After 15 minutes switched OFF the UV lamp.

6.6.4 Let the air flow as such for 15 minutes before sampling.

6.6.5 Dynamic pass box monitored for Air viable count for three consecutive days using Soyabean casein digest agar plates pre- incubated at 30 to 35^0C for at least 24-48 hrs before air sampling.

6.6.6 1000 Liter of air shall be sampled from two locations as shown in the fig as per **Exhibit-06**

6.6.7 After air sampling media plates shall be incubated first at 20 to 25^0C for 72 hrs and then shifted to 30 to 35^0C for next 48 hrs

6.6.8 The observations shall be recorded first after 72 hrs and then 48 hrs as per **Exhibit-06.**

6.6.9 Growth promotion test of the media shall be performed as per current SOP on "Growth promotion test".

ACCEPTANCE CRITERIA: <1 cfu per m^3.

6.7 PASSIVE AIR SAMPLING (SETTLE PLATE METHOD):

6.7.1 Sanitize the Dynamic pass box with 70% v/v Isopropyl alcohol properly.

6.7.2 Switch ON the UV lamp for 15 minutes. Switch ON the air flow also.

6.7.3 After 15 minutes switched OFF the UV lamp.

6.7.4 Let the air flow as such for 15 minutes before sampling.

6.7.5 Dynamic pass box monitored for Air viable count for three consecutive days using Soyabean casein digest agar plates pre- incubated at 30 to 35^{0}C for at least 24-48 hrs before air sampling

6.7.6 Divide the Dynamic pas box working table in to four equal rectangular parts and expose five plates. Out of five, one plate shall be in the middle of each rectangular division and one in the middle of the working table as shown in the diagram as per **Exhibit-07** for NLT 4 hrs.

6.7.7 Mark the location of sampling end date of exposure on each plate and then incubate them.

6.7.8 After air sampling media plates shall be incubated first at 20 to 25^{0}C for 72 hrs and then shifted to 30 to 35^{0}C for next 48 hrs.

6.7.9 The observations shall be recorded first after 72 hrs and then 48 hrs as per **Exhibit-07**.

6.7.10 Growth promotion test of the media shall be performed as per current SOP on "Growth promotion test" (SOP No.....).

ACCEPTANCE CRITERIA: <1 cfu per plate.

6.8 SURFACE MONITORING BY CONTACT PLATE METHOD:

6.8.1 Surface monitoring of flat surfaces of Dynamic pass box shall be done by this method for three consecutive days.

6.8.2 Contact plate of 55mm diameter shall be used for this purpose.

6.8.3 Brought the contact plate in contact with the surfaces and press it gently there so that surface which is to be monitored can be brought in contact with the surface.

6.8.4 Location of sampling and sampling date shall be marked on each plate.

6.8.5 Cover the plate with the lid and incubate them incubated first at 20 to 250C for 72 hrs and then shifted to 30 to 350C for next 48 hrs.

6.8.6 The observations shall be recorded first after 72 hrs and then 48 hrs as per Exhibit-08.

6.8.7 After sampling mop the area first with sterilized purified water and then with 70 % IPA.

ACCEPTANCE CRITERIA: NMT 3 cfu per plate.

Certificate of Analysis the 55 mm diameter contact plate shall be attached as **Annexure-04.**

6.9 RECOVERY STUDY:

OBJECTIVE

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

EQUIPMENT AND INSTRUMENT:

Calibrated Particle counter

PROCEDURE:

- The area is left aside for 20 minute before starting the measurement.
- Set particle counter in designated area, & set the sampler and collect the data for 0.5 µ & 5 µ particle.
- Switch off the AHU and continuously perform the Particle Count till the count goes beyond the acceptance criteria to next lower cleanliness level.
- Switch ON the AHU & continuously perform the Particle Count till time, the counts original at rest condition is achieved.
- The observations shall be recorded as per **Exhibit-E10**

ACCEPTANCE CRITERIA:

Recovery period should not be more than 15 minutes.

6.10 Any deviation observed during performance qualification shall be recorded in the observed deviation, corrective action and justification report section.

6.11 Observed deviation shall be reported to the department head and quality head.

6.12 If the observed deviation does not have any major impact on the qualification the final conclusion shall be provided.

6.13 If the observed deviation has major impact on the qualification, deviation shall be reported to the manufacturer for the corrective action and qualification activity shall be performed again.

7.0 ACCEPTANCE CRITERIA:

Qualification shall be considered acceptable when requirements listed in section 6.0 of this protocol has been fulfilled and all the components of Dynamic Pass Box are performing as per intended purpose.

8.0 QUALIFICATION REPORT:

The Qualification report shall consist of a summary document, in narrative form, which shall briefly describe the activity performed along with the observations recorded in relevant exhibits.

This report shall also include the related documents and attachments / annexure which were completed at the time of qualification activity.

9.0 APPROVAL OF QUALIFICATION REPORT:

The report shall be evaluated and proper references / conclusions / recommendations shall be recorded by quality assurance.

The Qualification report shall be evaluated and finally approved by Head Quality Assurance.

10.0 QUALIFICATION ACTIVITY PLAN:

Test Parameter	Max Time Interval	Remarks
Differential Pressure (To verify no cross contamination)	6 Months or when filter changed	For qualification activity data of three consecutive days shall be reported at the interval of 4 hours twice in each general shift**.**
Air velocity (To verify unidirectional flow or containment Conditions)	6 Months or when filter changed	Air velocities for containment systems and unidirectional flow protection systems to be measured.
Non viable air borne particle count (To verify cleanliness level)	6 Months or when filter changed	Dust particle counts to be carried out & result printouts to be produced.
Filter leakage test (HEPA filter integrity test) (To verify filter integrity)	6 Months or when filter changed	Filter penetration tests to be carried out by competent person to demonstrate filter media and filter seal integrity. Only required on HEPA filters.
Air flow patterns (To verify Laminarity)	6 Months or when filter changed	Air flow test shall be performed for checking the laminarity of the air down streams.
Air viable count by active air	6 Months or when	For qualification activity, area should be

Test Parameter	Max Time Interval	Remarks
sampling (Using Air Sampler) (To verify cleanliness level)	filter changed	monitored for air borne viable count daily for three consecutive days.
Passive Air sampling (settle plate method) (To verify cleanliness level)	6 Months or when filter changed	For qualification activity, area should be monitored for air borne viable count daily for three consecutive days.
Surface monitoring by contact plate method (To verify cleanliness level)	6 Months or when filter changed	For qualification activity, area shall be monitored for surface borne viable count by contact plate method for three consecutive days.
Recovery Study (To verify cleanliness level)	6 Months or when filter changed	For Recovery Study activity shall be monitored the particle count till the count goes beyond the acceptance criteria to assure that GSC will remains is working condition.

11.0 OBSERVED DEVIATION:

S. No.	Page No.	Point No.	Observed Deviation	Deviation Reported By	Deviation Approved By	Corrective Action Taken	Justification of Corrective Action	Corrective action taken and justification given by	

Report Approved By	
Department Head	**Quality Head**

12.0 LIST OF EXHIBITS / ANNEXURE:

12.1 LIST OF EXHIBITS:

Exhibit No.	Exhibit Title	No. of Pages
E01	Air Velocity	
E02	Non Viable Air Borne Particle Count	
E03	HEPA Filter Integrity Testing	
E04	Calibration Status Verification Checklist	
E05	Differential Pressure	
E06	Data sheet for viable count (by Active air sampler)	
E07	Data sheet for viable count (by Settle plate method)	
E08	Data Surface monitoring for viable count (by Contact plate)	
E09	Air Flow Pattern Test	
E10	Recovery Test Report	
Total No. of Pages		

12.2 LIST OF ANNEXURE:

Annexure No.	Annexure Title	No. of Pages
1.	Training Record	
2.	Test Reports	
3.	Video Compact Disc for Air Flow Pattern	
4.	Calibration Certificates of Instruments	
Total No. of Pages		

13.0 REFERENCE DOCUMENTS

- ISO 14644 of Clean Rooms and Associated Controlled Environments.
- Validation Master Plan.
- Schedule - M – “Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products.”

EXHIBIT-E01

AIR VELOCITY

Date of test_____

Name of the Instrument used for test_____

Make_____ Model_____

Date of calibration_____ Due date of calibration_____

Sr. No._____

Location	Air velocity v (FPM)
V1	
V2	
V3	
V4	
V5	
Average	
Witnessed by	

Acceptance Criteria: The Average air velocity shall be within 90 ± 20% FPM.

Remarks: Results are **within/ not within** limit**.**

Reviewed By:_____ _____ _____

(QC) (Name) (Sign) (Date)

Verified By:_____ _____ _____

(QA) (Name) (Sign) (Date)

EXHIBIT – E02

NON VIABLE AIR BORNE PARTICLE COUNT

Date of test_____ Desired Cleanliness level_____

No. of locations to be sampled_____ Witnessed By_____

Instrument used for test_____ Make_____

Model_____ Sr. No_____

Date of calibration_____ Due date of calibration_____

Volume of air sampled _____ Time for which air sampled_____

Location	Particle count 0.5 µ per m^3				Particle count 5.0 µ per m^3			
	1	2	3	Avg.	1	2	3	Avg.
L1								
L2								
L3								
L4								
L5								
Mean of average, M= (A_1+A_2 + ----- + A_n) / n								

Acceptance criteria:

Class	Maximum permitted no of particles / m^3 of air	
	≥ 0.5 µm	**≥ 5.0 µm**
100	3520	29

Remarks: Results are **within/ not within** limit**.**

Reviewed By:_____ _____ _____

(QC) (Name) (Sign) (Date)

Verified By:_____ _____ _____

(QA) (Name) (Sign) (Date)

EXHIBIT-E03

HEPA FILTER INTEGRITY TESTING

Date of test_____

Name of the Instrument used for test_____

Make_____ Model_____

Date of calibration_____ Due date of calibration_____

Sr. No._____ Concentration of PAO upstream_____

Maximum Downstream Concentration of PAO observed	Remarks	Witnessed By

Acceptance criteria: NMT 0.01% PAO shall penetrate across the HEPA filter and no leakage shall be observed from the fitment.

Remarks: Results are **within/ not within** limit**.**

Reviewed By:_____ _____ _____

(QC) (Name) (Sign) (Date)

Verified By:_____ _____ _____

(QA) (Name) (Sign) (Date)

EXHIBIT-E04

CALIBRATION STATUS VERIFICATION CHECKLIST

Equipment Name / Description: Dynamic Pass Box

Tag No. :

Location : Microbiology Lab (QA/QC Block)

S.No.	Instrument Name	Instrument Code / Sr. No.	Calibration Certificate No.	Calibration Due On
1.	Differential Pressure Gauge			
2.	Anemometer			
3.	Laser Particle Counter			
4.	Photometer			

Remarks: Calibration status is OK / Not OK

Reviewed By:_____ _____ _____

(QC) (Name) (Sign) (Date)

Verified By:_____ _____ _____

(QA) (Name) (Sign) (Date)

EXHIBIT – E05

Differential Pressure

Instrument: **Instrument ID:**

Date	Observed Differential pressure, DP (mm of WC)		
	Time	DP	Observed by

Acceptance criteria: 10-15mm of WC.

Remarks: Observations are **within/ not within** limit**.**

Checked By: _____ _____ _____

(QA) **(Name)** **(Sign)** **(Date)**

Verified By: _____ _____ _____

(QA) **(Name)** **(Sign)** **(Date)**

EXHIBIT –E06

DATA SHEET FOR VIABLE PARTICLE TEST (ACTIVE AIR SAMPLING)

Media used_____

1st Incubation temp/period_____ 2st Incubation temp/period_____

Incubator ID (20º to 25ºC)_____ Incubator ID (30º to 35º C)_____

Sampling location	Class	Exposure Date: Completion Date: Plate Exposure Time:		Exposure Date: Completion Date: Plate Exposure Time:		Exposure Date: Completion Date: Plate Exposure Time:		Limit CFU/m³
		Observation (72 Hrs) CFU/m³	Observation (120 Hrs) CFU/m³	Observation (72 Hrs) CFU/m³	Observation (120 Hrs) CFU/m³	Observation (72 Hrs) CFU/m³	Observation (120 Hrs) CFU/m³	

Positive control (+): _____-: denotes characteristic growth Negative control (-): _____ -: denotes no growth

Remarks: Observations are **within/ not within** limit**.**

Checked By: _____ _____ _____

(QA) **(Name)** **(Sign)** **(Date)**

Verified By: _____ _____ _____

(QA) **(Name)** **(Sign)** **(Date)**

EXHIBIT –E07

DATA SHEET FOR VIABLE PARTICLE TEST (SETTLE PLATE METHOD)

Media used_____

1st Incubation temp/period_____ 2st Incubation temp/period_____

Incubator ID (20º to 25ºC)_____ Incubator ID. (30º to 35º C)_____

Sampling location	Class	Exposure Date: Completion Date: Plate Exposure Time:		Exposure Date: Completion Date: Plate Exposure Time:		Exposure Date: Completion Date: Plate Exposure Time:		Limit CFU/4hrs
		Observation (72 Hrs) CFU/4hrs	Observation (120 Hrs) CFU/4hrs	Observation (72 Hrs) CFU/4hrs	Observation (120 Hrs) CFU/4hrs	Observation (72 Hrs) CFU/4hrs	Observation (120 Hrs) CFU/4hrs	

Positive control (+): _____-: denotes characteristic growth Negative control (-): _____ -: denotes no growth

Remarks: Observations are **within/ not within** limit**.**

Checked By:
(QA) _____ **(Name)** _____ **(Sign)** _____ **(Date)**

Verified By:
(QA) _____ **(Name)** _____ **(Sign)** _____ **(Date)**

EXHIBIT –E08

SURFACE MONITORING FOR VIABLE COUNT (BY CONTACT PLATE METHOD)

Type of plate used_____

1st Incubation temp/period_____ 2st Incubation temp/period_____

Incubator ID (20° to 25°C)_____ Incubator ID. (30° to 35° C)_____

Exposure Date: _____ Completion Date: _____

Sampling location	Class	Observation (72 Hrs) CFU/plate	Observation (120 Hrs) CFU/plate	Limit CFU/plate

Acceptance Criteria: Limits for class 100 is not more than 3 CFU/contact plate.

Remarks: Observations are **within/ not within** limit**.**

Checked By: _____ _____ _____

(QA) **(Name)** **(Sign)** **(Date)**

Verified By: _____ _____ _____

(QA) **(Name)** **(Sign)** **(Date)**

EXHIBIT –E09

AIR FLOW PATTERN TEST

Instrument Name		Date of Test	
Make		Instrument ID.	

Area	Air Flow Pattern should be from Supply to Riser	Air Flow Pattern should Observed Positive Pressure to Negative Pressure	Visibility of Smoke Generated (Yes/No)

Acceptance criteria: The Air flow direction should be move in a downward direction.

Remarks: Air flow direction **Comply/does not comply** as per the acceptance criteria.

Checked By: _____ _____ _____

(QA) **(Name)** **(Sign)** **(Date)**

Verified By: _____ _____ _____

(QA) **(Name)** **(Sign)** **(Date)**

EXHIBIT –E10

RECOVERY TEST REPORT			
Equipment Name		**Equipment Tag No.**	
Room Name / No.		**Grade**	
Testing Instrument		**Instrument ID / S. No.**	
Calibration Done on		**Calibration Due on**	

Initial Count	**≥ 0.5 µm**	**≥ 5.0 µm**

Counts/Minute	**≥ 0.5 µm**	**≥ 5.0 µm**
0 min		
1 min		
2 min		
3 min		
4 min		
5 min		
6 min		
7 min		
8 min		
9 min		
10 min		
11 min		
12 min		
13 min		
14 min		
15 min		
Recovery time (100:1) in minute		

Acceptance Criteria: Recovery period should not be more than 15 minutes.

Conclusion: The recovery time for Room No. .....is .....minutes.

Checked By: _____ _____ _____

(QA) **(Name)** **(Sign)** **(Date)**

Verified By: _____ _____ _____

(QA) **(Name)** **(Sign)** **(Date)**

Annexure – 01

TRAINING RECORD

Equipment Name:	Dynamic Pass Box
Equipment ID No.:	
Location:	Microbiology Lab (QA/QC Block)
No. of Pages:	

Annexure – 02

TEST REPORTS

Equipment Name:	Dynamic Pass Box
Equipment ID No.:	
Location:	Microbiology Lab (QA/QC Block)
No. of Pages:	

Annexure – 03

VIDEO COMPACT DISC FOR AIR FLOW PATTERN

Equipment Name:	Dynamic Pass Box
Equipment ID No.:	
Location:	Microbiology Lab (QA/QC Block)
No. of Pages:	

Annexure – 04

CALIBRATION CERTIFICATES OF INSTRUMENTS

Equipment Name:	Dynamic Pass Box
Equipment ID No.:	
Location:	Microbiology Lab (QA/QC Block)
No. of Pages:	