



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

**Title:** Cleaning, Calibration and Operation of Pass Box

<b>SOP No.:</b>		<b>Department:</b>	Microbiology
		<b>Effective Date:</b>	
<b>Revision No.:</b>	00	<b>Revision Date:</b>	
<b>Supersede Revision No.:</b>	Nil	<b>Page No.:</b>	1 of 7

### 1.0 OBJECTIVE:

To lay down procedure for cleaning, calibration and operation of pass boxes.

### 2.0 SCOPE:

This SOP is applicable for pass boxes, Make - Klenz Port in microbiology laboratory.

### 3.0 RESPONSIBILITY:

Prepared by - Executive Microbiology

Checked by - Assistant Manager Microbiology / QC

Approved by - Head QA, QC

### 4.0 PROCEDURE:

#### 4.1 Operation of Static Pass Box

- 4.1.1 Ensure that the pas box is clean internally and externally before operating it.
- 4.1.2 Connect the plug of static pas box to the main power supply.
- 4.1.3 Press the main power switch button on.
- 4.1.4 Gently press the power button to switch on the pass box, provided on the front panel of the pass box.
- 4.1.5 Power button light (Red light) start glowing indicating pass box is on.
- 4.1.6 UV light of pass box also starts glowing with start of pass box.
- 4.1.7 Switch on the UV light tube 30 minute before routines use.
- 4.1.8 Record the burning hours of U.V. light daily in the morning.
- 4.1.9 Maintain the record of burning hours of U.V. light as per Annexure - I.
- 4.1.10 Open the door of pass box from one side by pressing the door release button provided on the panel of the pass box.
- 4.1.11 Place all the material to be transferred in the pass box.



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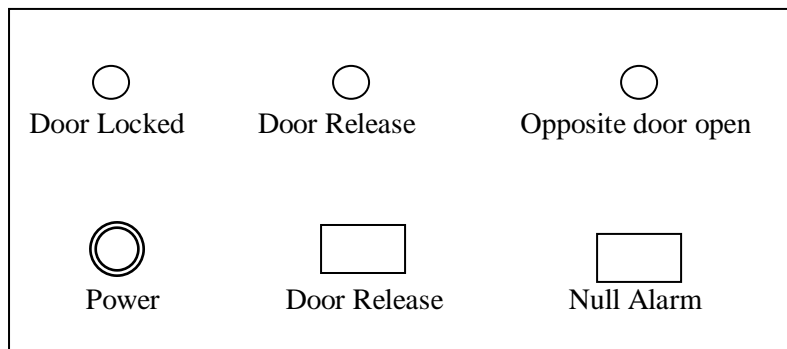
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4.1.12 Close the door carefully, ensuring that the interlocking system has been engaged.

4.1.13 Transfer material is to be removed by pressing the door release button provided on the panel of the opposite side of the pass box.

4.1.14 Carefully remove all the material from the pass box and close the door .

4.1.15 Panel of static pass box.



## 4.2 Operation of Dynamic Pass Box

4.2.1 Ensure that the pas box is clean internally and externally before operating it.

4.2.2 Connect the plug of static pas box to the main power supply.

4.2.3 Press the main power switch button on.

4.2.4 Gently press the power button to switch on the pass box, provided on the front panel of the pass box.

4.2.5 Power button light (Red light) start glowing indicating pass box is on.

4.2.6 Gently press the power button to start the motor and Magnehelic gauge, provided on the front panel of the pass box.

4.2.7 Switch on the airflow and light by pressing the button provided on the front panel of the pass box.

4.2.8 Check the pressure difference in the Magnehelic gauge and it should be between 10 - 15 mm of water.

4.2.9 Magnehelic gauge readings of the pass box should be within the set limit. It should be zero when pass box is in off position.

4.2.10 Record the Magnehelic gauge reading (pressure differential) twice in a day i.e. the morning and in the evening.

4.2.11 Maintain the record of Magnehelic gauge reading (pressure differential) as per Annexure - II.



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4.2.12 Open the door of pass box from one side by pressing the door release button provided on the panel of the pass box.

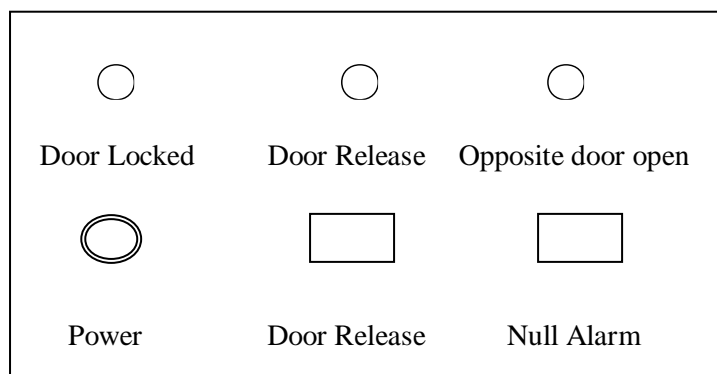
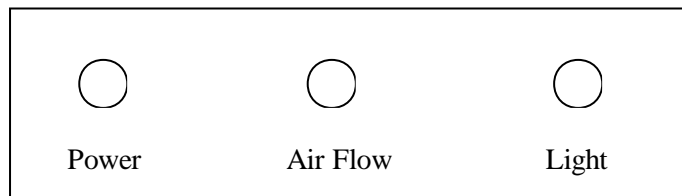
4.2.13 Place all the material to be transferred in the pass box.

4.2.14 Close the door carefully, ensuring that the interlocking system has been engaged.

4.2.15 Transfer material is to be removed by pressing the door release button provided on the panel of the opposite side of the pass box.

4.2.16 Carefully remove all the material from the pass box and close the door.

4.2.17 Panel of dynamic pass box.



### 4.3 Cleaning

4.3.1 Switch off the main power supply of the pass box and remove the pass box plug from the main power supply.

4.3.2 Clean the pass box internally and externally by clean lint free cloth soaked in 70 % IPA or any other approved disinfectant solution.

### 4.4 Calibration

4.4.1 UV usage meter of the pass box is to be calibrated once in six months by service contractor.



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4.4.2 Check the intensity of UV light tube with the help of UV intensity meter once in a month or when a UV light tube is replaced. If the intensity falls below 70% of the initial intensity the UV light tube should be changed.

4.4.3 Validate the bactericidal and fungicidal efficacy of UV radiation using the plate count method once in six months or after change of UV light tube.

4.4.4 In case validation fails, replace the UV light tube and repeat the above test.

4.4.5 Magnehelic gauge is to be calibrated once in six months by service contractor.

4.4.6 HEPA filter testing is to be done once in six months.

### 5.0 SAFETY & PRECAUTIONS:

5.1 At the time of opening of one door of pass box opposite side door always be close.

5.2 Ensure that UV light tube is changed after every 5000 burning hours (Burning hours are recorded on calibrated UV usages meter).

### 6.0 REVISION HISTORY:

Revision No.	Reason for Revision	Superseded from & Date
00	First Issue	-----

### 7.0 REFERENCES:

Not applicable.

### 8.0 ABBREVIATIONS

SOP : Standard Operating Procedure

No. : Number

% : Percentage

IPA : Isopropyl Alcohol

HEPA : High Efficiency Particulate Air

UV : Ultra Violet



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### 9.0 ANNEXURES

**Annexure - I :** U.V. light burning hour's record of pass box

**Annexure - II :** Magnehelic gauge reading (pressure differential) of pass box



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### ANNEXURE - I

#### UV LIGHT BURNING HOUR'S RECORD OF PASS BOX

**Location:** \_\_\_\_\_ **ID - :** \_\_\_\_\_

Date	Burning hours	Recorded by	Checked by



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### ANNEXURE II

#### MAGNEHELIC GAUGE READING (PRESSURE DIFFERENTIAL) OF PASS BOX

**Location:** \_\_\_\_\_ **ID - :** \_\_\_\_\_

Date	Location of Pass box	Pass box ID	Magnehelic Gauge Reading (mm of water)				Checked by	
			Before switching on	After switching on (10 - 15 mm of water )				
				Morning	Recorded by	Evening		Recorded by
	MLT room to sterile corridor							
	MLT room to incubator room - I							
	Incubator room - I to sterile corridor							
	Media preparation to cooling zone							
	MLT room to sterile corridor							
	MLT room to incubator room - I							
	Incubator room - I to sterile corridor							
	Media preparation to cooling zone							
	MLT room to sterile corridor							
	MLT room to incubator room - I							
	Incubator room - I to sterile corridor							
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