



STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Procedure for Operation, Cleaning and Maintenance of Dynamic Pass Box	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a procedure for Operation, Cleaning and Maintenance of Dynamic Pass Box.

2.0 SCOPE:

This SOP is applicable for Operation, Cleaning and Maintenance of Dynamic Pass Box provided in Hot Zone of Microbiology Section of Quality Control Laboratory.

3.0 RESPONSIBILITY:

Officer / Executive-QC

4.0 ACCOUNTABILITY:

Head QC

5.0 PROCEDURE:

5.1 INSTRUCTION:

Blower of every Dynamic Pass Box shall be kept 24 hrs. switched on.

5.2 OPERATION:

5.2.1 Switch "ON" the Main Switch.

5.2.2 Switch "ON" the UV Light for 30 minutes before material transfer.

5.2.3 Check the Pressure drop across the HEPA Filter and ensure that it is between 10-15 mm of water on Magnehelic Gauge.

5.2.4 Open the door and ensure that UV Lights is ON and Tube Light automatically glows just after opening of the Door.

5.2.5 If any abnormal sound is observed from the unit, the unit must be checked for its Wear and Tear.

5.2.6 Sanitize external surface of all the containers or objects to be transferred through this Dynamic Pass Box with 70 % IPA Solution.

5.2.7 Before transferring the material check and ensure that Cooling Zone Side Door of Dynamic Pass Box closed.

5.2.8 Open the Hot Zone side door of the Dynamic Pass Box and transfer all the Sanitized Containers / objects inside the Dynamic Pass Box and close the door.

5.2.9 For ensuring the working of blower checks the pressure differential in Magnehelic gauge.

5.2.10 Open the Cooling Zone Side Door of Dynamic Pass Box and take out all the containers from Dynamic Pass Box in to the Cooling Zone and close the Cooling Zone side door of the Dynamic Pass Box.



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

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5.2.11 UV Tube shall be replaced after completion of 1000 hours.

5.2.12 Record the observed Pressure Differential with help of The Display Needle of Magnehelic Gauge daily while using pass box in **Annexure-I**, Titled “**Dynamic Pass Box Utilization Record**”.

5.2.13 Record the Material /product details in the **Annexure-I (Dynamic Pass Box Utilization Record)**.

6.0 REFERENCES:

Not Applicable

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Dynamic Pass Box Utilization Record	

ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

- Controlled Copy No.01 Quality Assurance Department
- Controlled Copy No.02 Quality Control Department
- Master Copy Quality Assurance Department

9.0 ABBREVIATIONS:

HEPA High Efficiency Particulate Air Filter
Ltd. Limited
No. Number

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Details of Changes	Reason for Change	Effective Date	Updated By

