

PHARMA DEVILS PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE				
Department: Production (External Preparation)	SOP No.:			
Title: Operation and Cleaning of Dynamic Pass Boxes	Effective Date:			
Supersedes: Nil	Review Date:			
Issue Date:	Page No.:			

1.0 OBJECTIVE:

To lay down a Procedure for Operation & Cleaning of Dynamic Pass Boxes.

2.0 SCOPE:

This SOP is applicable for Operation & Cleaning of Dynamic Pass Boxes.

3.0 RESPONSIBILITY:

Production Officer/Executive

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

- HEPA High Efficiency Particulate Air
- QA Quality Assurance
- QC Quality Control
- SOP Standard Operating Procedure
- UV Ultra Violet

6.0 **PROCEDURE**:

6.1 **OPERATION:**

- **6.1.1** Ensure that the Dynamic Pass Box is clean properly.
- **6.1.2** Check the pressure drop across the HEPA filter and ensure that between 8 to 25 mm of water on Magnehelic gauge.
- **6.1.3** Mop the external surface of all the containers or articles to be transferred through the Dynamic Pass Box with dry clean lint free cloth.
- **6.1.4** Check and ensure that other side door of Dynamic Pass Box is closed.
- **6.1.5** Open the door of the Dynamic Pass Box by pressing DR Button and place the sanitized containers / articles inside the Dynamic Pass Box.
- 6.1.6 Close the door of Dynamic Pass Box and ring the bell.
- 6.1.7 Open the door from the other side of Dynamic Pass Box and receive the material.



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6.1.8 After completion of activity switch 'OFF' the Blower.

6.2 CLEANING:

- 6.2.1 Ensure that the Blower is switched "OFF".
- **6.2.2** Clean the inside surface of the Dynamic Pass Box with clean lint free cloth.
- **6.2.3** Clean the inside surface of the Dynamic Pass Box with clean lint free mop dipped in scheduled disinfectant followed by dry lint free mop.
- **6.2.4** Clean the pass box from outside by using lint free mop dipped in scheduled disinfectant followed by dry lint free mop.
- **6.2.5** Dynamic Pass Boxes shall be cleaned once in a day or whenever required.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Differential Pressure Record (Dynamic Pass Box)	

ENCLOSURE: SOP Training Record

8.0 **DISTRIBUTION:**

٠	Controlled Copy No. 01	Quality Assurance

- Controlled Copy No. 02 Production
- Master Copy
 Quality Assurance

9.0 **REFERENCES:**

Not Applicable.

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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



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ANNEXURE-I

DIFFERENTIAL PRESSURE RECORD (DYNAMIC PASS BOX)

Department: Equipment ID. No: Month:

Area: Frequency: Before and after Operation Year:

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Limit: Between 8 mm & 25 mm of water gauge

S.No.	Date	Time	Observed Reading	Observed By Officer / Executive	Checked By Officer/ Executive	Remarks
				Warehouse / QC	QA	