



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

**Title:** Operation and Cleaning of Static Pass Box, Dynamic Pass Box & Dynamic Garment Storage Cabinet

<b>SOP No.:</b>		<b>Department:</b>	Production
		<b>Effective Date:</b>	
<b>Revision No.:</b>	00	<b>Revision Date:</b>	
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### 1.0 OBJECTIVE:

To lay down a procedure for Operation and Cleaning of Static Pass Box, Dynamic Pass Box & Dynamic Garment storage cabinet.

### 2.0 SCOPE:

This SOP is applicable for Operation and Cleaning of Static Pass Box, Dynamic Pass Box & Dynamic Garment storage cabinet provided in parenteral Production area.

### 3.0 RESPONSIBILITY:

Officer / Executive Production

### 4.0 ACCOUNTABILITY:

Head Production

### 5.0 ABBREVIATIONS:

Ltd.	Limited
No.	Number
QA	Quality Assurance
SOP	Standard Operating Procedure
UV	Ultra Violet
IPA	Iso-Propyl alcohol
DGSC	Dynamic Garment storage cabinet
DP	Difference pressure
PW	Purified Water
WFI	Water for Injection
NLT	Not Less Than

### 6.0 PROCEDURE:

#### 6.1 OPERATION OF STATIC PASS BOX :

- 6.1.1 Ensure that the Static pass box is clean.
- 6.1.2 Open the door and place the material container inside the pass box.
- 6.1.3 Close the door of static pass box and inform to another side operator by alarm.
- 6.1.4 The operator of another side shall open the door of pass box and receive the materials.
- 6.1.5 The operator shall check the status label and place the material at defined location.
- 6.1.6 After receipt of material close the door.
- 6.1.7 If the static pass box is not working properly inform to Head Engineering by Work order for further rectification of breakdown and shall be followed the Entry, Exit & aseptic practices as per respective SOP's of area.



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**6.1.8** After rectification breakdown, Static pass box shall be clean as define procedure and record the same in respective log of equipment's.

### **6.1.9 Cleaning of Static Pass Box:**

**6.1.9.1** Cleaning of static pass box from outside and inside using a **dry lint free cloth** to remove any adherent material.

**6.1.9.2** Then wipe with **70 % IPA** using **lint free cloth** and then again clean with dry lint free cloth.

**6.1.9.3** Record the Usage & cleaning activities in **Annexure-I** Titled as "**Static Pass Box Cleaning & Usage Log**".

**6.1.9.4 Cleaning Frequency:** Daily once/whenever required/after Preventive maintenance activity/after rectification of breakdown.

## **6.2 OPERATION OF DYNAMIC PASS BOX:**

### **6.2.1 Instructions:**

**6.2.2** Blower & UV light of every Dynamic Pass Box shall be kept "**ON**" always except Cleaning, Breakdown, and Preventive maintenance and during active air sampling.

**6.2.3** Avoid the direct exposure of UV line on skin & eye.

**6.2.4** Ensure that transfer activity of BI indicator /process indicator(un -exposed /exposed indicator and media plates in closed S.S bin /container by exclusion of UV exposure to avoid the discrepancy in data interpretation of (un -exposed /exposed ) indicator (s).

**6.2.5** Use the dynamic pass box after **10 minutes** from cleaning and sanitization as well as after any breakdown rectification /Preventive maintenance.

**6.2.6** No UV Exposure, Hold & Sanitization is mandate, if may be consider for better control.

**6.2.7** Before transferring the material check and ensure that Inner Side Door of Dynamic Pass Box closed.

**6.2.8** Use filtered disinfectant solution in aseptic area to be transferred through Dynamic pass Box from lower grade area to higher grade area.

### **6.2.9 Operation:**

**6.2.10** Ensure that the Dynamic pass box is clean.

**6.2.11** Switch "**ON**" the Main Switch.

**6.2.12** Check the Pressure drop across the HEPA Filter and ensure that it should be within **10 – 20 mm of water** on Magnehelic Gauge.



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- 6.2.13** Check the Pressure drop across the HEPA Filter and ensure that it should be within **05 – 15 mm of water** on Magnehelic Gauge.
- 6.2.14** Check the Pressure drop across the Pre Filter and ensure that it should be within **0.6 – 4 mm of water** on Magnehelic Gauge.
- 6.2.15 In case of Sterile material container OR Three piece vial:** Before transferring into the dynamic pass box, material shall be Sanitize the external surface of item(s) /container / material with **70 % IPA** & then sanitize with **5%Virosil/ Silvicide** solution from top to bottom direction (unidirectional). Intactness of sterile article shall be evaluated.
- 6.2.16 In case of General material:** Before transferring into the dynamic pass box, material shall be Sanitize the external surface of item(s) /container / material with **70 % IPA** solution from top to bottom direction (unidirectional).
- 6.2.17** Open the dynamic pass box door by pressing the switch to release the interlocking of loading /unloading side door as per applicability of material transfer as one time on door opening will be applicable.
- 6.2.18** Place the item(s)/container/Material to be transferred in the dynamic pass box. Allow to hold the material for **10 minutes of UV** exposure inside dynamic pass box (as per auto interlocking timer or hold the material for **NLT 10 minutes UV** exposure in Dynamic pass which are excluded with auto inter locking).
- 6.2.19** Record the Equipment usage details in **Annexure-II** Titled as **“Dynamic Pass Box Cleaning & Usage Log”**.
- 6.2.20** On completion of UV exposure, intimate the person present in other side of dynamic pass box via bell available in dynamic pass box or telephone to unload the item(s)/container/ Material from higher grade side of the pass box and sanitize phone after use.
- 6.2.21** Unload the item(s) /container/material (after completion UV exposer time) by opening the dynamic pass box door and kept at clean SS pallets OR suitable place.
- 6.2.22** If the Dynamic pass box is not working properly inform to Engineering by Work order for further rectification of breakdown and shall be followed the Entry, Exit & aseptic practices as per respective SOP's of area.
- 6.2.23** After rectification breakdown, Dynamic pass box shall be clean as define procedure and record the same in respective log of equipment's.
- 6.2.24 Cleaning of Dynamic Pass Box:**
- 6.2.24.1** Ensure the UV light & Blower **“Off”** condition before initiation of cleaning, Material keeping or any Preventive activity/break down.
- 6.2.24.2** Cleaning activity of dynamic pass box shall be performed by lower grade area.
- 6.2.24.3** Perform dry cleaning of dynamic pass Box by removal of left over paper/polybag/ corrugated material and dry moping with lint free mop, mop external surface direction



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which includes the surface gauge indicator followed by wet cleaning with lint free mop soaked in PW/WFI (as per applicability) followed by sanitization with **70% IPA**.

- 6.2.24.4** Sanitize the outer surface of Dynamic Pass Box and close the lower grade side door.
- 6.2.24.5** Switch “ON” the main switch.
- 6.2.24.6** Switch “ON” the UV light & Blower and let it being operation for **10 minutes**.
- 6.2.24.7** Check the Pressure drop across the HEPA Filter and ensure that it should be within **10 – 20 mm of water** on Magnehelic Gauge.
- 6.2.24.8** Check the Pressure drop across the HEPA Filter and ensure that it should be within **05 – 15 mm of water** on Magnehelic Gauge.
- 6.2.24.9** Check the Pressure drop across the PRE Filter and ensure that it should be within **0.6 – 4 mm of water** on Magnehelic Gauge.
- 6.2.24.10** Record the Equipment cleaning details in **Annexure-II** Titled as “**Dynamic Pass Box Cleaning & Usage Log**”.
- 6.2.24.11** **Cleaning & DP monitoring Frequency:** Daily once / whenever required / after Preventive maintenance activity/after rectification of breakdown.

### **6.3 OPERATION OF DYNAMIC GARMENT STORAGE CABINET:**

#### **6.3.1 Instructions:**

**6.3.2** Blower & UV light of every DGSC shall be kept “ON” always except Cleaning, Breakdown & Preventive maintenance.

**6.3.3** Switch “OFF” the UV lights before opening of the door to avoid the direct exposure of UV line on skin & eye.

#### **6.3.4 Operation:**

**6.3.5** Ensure that the DGSC is clean.

**6.3.6** Switch “ON” the Main Switch.

**6.3.7** Switch “ON” the UV Light and blower **10 minutes** before starting work.

**6.3.8** Observe the reading on Magnehelic Gauge and ensure that it is between **10 to 20 mm** of water.

**6.3.9** If any abnormal sound is observed from the Unit, the Unit must be checked for its wear and tear.

**6.3.10** Switch “OFF” the UV light and open the door and place all the sterile set of garments inside the Dynamic Garment Storage Cabinet.

**6.3.11** Close the door and ensure that even after closer of door laminar air is continuously blowing inside the garment storage cabinet and Switch “ON” the UV lights.



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**6.3.12** Switch “OFF” the UV lights before opening of the door.

**6.3.13** If the DGSC is not working properly inform to Head Engineering by Work order for further rectification of breakdown and shall be followed the Entry, Exit & aseptic practices as per respective SOP’s of area.

**6.3.14** After rectification breakdown, DGSC shall be clean as define procedure and record the same in respective log of equipment’s.

**6.3.15 Cleaning of Dynamic Garment Storage Cabinet:**

**6.3.15.1** Switch “OFF” the laminar air flow unit of Dynamic Sterile Garment Storage Cabinet.

**6.3.15.2** Switch “OFF” the UV light.

**6.3.15.3** Remove any kind of Material, Particles etc. and clean the inner surface with lint free cloth or sponge.

**6.3.15.4** Spray **70% IPA** at the inner surface of garment cabinet and inner surface of the door and wipe it with dry sponge.

**6.3.15.5** Close the door of Dynamic Garment Storage Cabinet and mop the outside surface with **70% IPA**.

**6.3.15.6** Switch “ON” the electric supply for supply of laminar air flow inside the dynamic sterile garment storage cabinet and switch “ON” the UV light and let it being operation for **10 minutes**.

**6.3.15.7** Record the cleaning details in “**Dynamic Garment Storage Cabinet Cleaning & Usage Log**” as per Format shown in **Annexure-III**.

**6.3.15.8 Cleaning & DP monitoring Frequency:** Daily once/whenever required/after Preventive maintenance activity/after rectification of breakdown.

**6.3.15.9** Record the cleaning activity in respective equipment log book.

**6.4 UV BURNING RECORD FOR DYNAMIC PASS BOX & DYNAMIC GARMENT STORAGE CABINET:**

**6.4.1** Replace the UV light on **Yearly basis (±7 days)** or due to any malfunctioning, whichever is earlier.

**6.4.2** Justification of frequency as vendor recommendation is **9000 hrs. (365 days x 24 = 8760 hrs.)**

**6.4.3** Schedule of UV replacement shall mention on yearly basis as **Annexure- IV** titled as “**Schedule of UV light replacement of Dynamic pass box & Dynamic garment storage cabinet**”.

**6.4.4** Schedule shall be prepared by production and hand over to QA for further approval.



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**6.4.5** QA shall retain the mater copy & issued the control copy of respective manufacturing area as per procedure.

**6.4.6** UV light replacement status label shall be affix on each equipment as **Annexure-V** titled as “**Status Label UV light replacement**”.

**6.4.7** If any update in facility w.r.t. Dynamic pass box & Dynamic garment storage cabinet, schedule shall be updated next year accordingly.

### 6.5 CLEANING OF ASSOCIATED FILTERS:

**6.5.1** Cleaning of associated filters shall be performed as per **SOP**.

**6.5.2** Operation activities shall be recorded in respective log of equipment along with cleaning, preventive maintenance etc.

### 7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Static Pass Box Cleaning & Usage Log	
Annexure-II	Dynamic Pass Box Cleaning & Usage Log	
Annexure-III	Dynamic Garment Storage Cabinet Cleaning & Usage Log	
Annexure-IV	Schedule of UV Light Replacement Of Dynamic Pass Box & Dynamic Garment Storage Cabinet	
Annexure-V	Status Label UV light replacement	

**ENCLOSURES:** SOP Training Record

### 8.0 DISTRIBUTION:

- Controlled Copy No.01      Quality Assurance
- Controlled Copy No.02      Production
- Master Copy                      Quality Assurance

### 9.0 REFERENCE

Not Applicable.

### 10.0 REVISION HISTORY:

#### CHANGE HISTORY LOG

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













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### ANNEXURE-V

#### UV LIGHT REPLACEMENT LABEL

Equipment Name	
Equipment ID	
UV light installation date	
UV light replacement due date	
Done By (Sign. & Date)	
Checked By (Sign. & Date)	