



PHARMA DEVILS

WAREHOUSE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Warehouse	SOP No.:
Title: Operation and Cleaning of Dynamic Pass Boxes for Injection Section	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

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

2.0 SCOPE:

This SOP is applicable for Operation & Cleaning of Dynamic Pass Boxes used in Raw Material Store for Injection section.

3.0 RESPONSIBILITY:

Operating Person – Warehouse/QC

4.0 ACCOUNTABILITY:

Head – Warehouse/QC

5.0 ABBREVIATIONS:

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

6.0 PROCEDURE:

6.1 Operation of Dynamic Pass Box:

6.1.1 Instruction:

6.1.1.1 Blower & UV light of every Dynamic Pass Box shall be kept “ON” 24x7, except Cleaning, Breakdown, Preventive maintenance and during active air sampling. Ensure Blower & UV light should be open immediately after above mentioned activity.

6.1.1.2 Avoid the direct exposure of UV light over skin & eye.

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

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

6.1.1.5 Before transferring the material check and ensure that Inner Side Door of Dynamic Pass Box Should be closed.

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

6.2 Operation:



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6.2.1.1 Ensure that the Dynamic Pass Box is clean properly.

6.2.1.2 Check the Switch “ON” the UV Light before starting the activity and blower 24 hours continue.

6.2.1.3 Check the pressure drop across the HEPA Filter and ensure that it should be within 10-20 mm on Magnehelic Gauge and record in **Annexure-I**.

6.2.1.4 If Pre filter and HEPA filter both are available in Dynamic Pass Box ensure that Pre filter pressure should be within 0.6 to 4 mm of water and HEPA filter pressure should be within 5 to 15 mm of water and record it in **Annexure**.

6.2.1.5 The sterile & Non Sterile material /container transfer to aseptic area shall be kept in under UV exposure in dynamic pass box and record in **Annexure-I**.

Remark: (i) For Sterile material 10 minutes & Non Sterile material 5 minutes shall be kept in under UV.

6.2.1.6 Sterile Raw Materials container mopping outer surface & bottom surface with 5% Silvicide/ Virosil.

6.2.1.7 Open the door by pressing DR Button and ensure that UV light shall be OFF automatically.

6.2.1.8 Clean the external surface of all the containers with dry clean lint free cloth.

6.2.1.9 Check and ensure that other side door of Dynamic Pass Box is closed.

6.2.1.10 Open the door of the Dynamic Pass Box by pressing DR Button and place the cleaned containers / articles inside the Dynamic Pass Box.

6.2.1.11 Close the door of Dynamic Pass Box after expose in UV and ring the bell.

6.2.1.12 Open the door from the other side of Dynamic Pass Box and receive the material.

6.2.1.13 Close the door of the Dynamic Pass Box after getting the material out and ensure that UV light gets ON.

6.2.1.14 Warehouse officer/executive shall enter the Operation & others details of dynamic pass box in **Annexure-I**, titled as “**Dynamic Pass Box Log**”.

6.3 UV Burning Record For Dynamic Pass Box:

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

6.3.2 Justification of frequency as vendor recommendation is **9000 Hrs (365 days X 24 = 8760 hrs.)**

6.3.3 Schedule of UV replacement shall mention on yearly basis in **Annexure** titled as “**Schedule of UV light replacement Record**”.



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- 6.3.4 Schedule shall be prepared by Warehouse and hand over to QA for further approval & verification.
- 6.3.5 UV light replacement status label shall be affix on each equipment as **Annexure** titled as “**Status Label of UV light replacement.**”
- 6.3.6 If the Dynamic pass box is not working properly inform to Engineering by mail or Work order for further rectification of breakdown and shall be followed the Entry, Exit & aseptic practices as per respective SOP’s of area.
- 6.3.7 After rectification breakdown, Dynamic pass box shall be clean as define procedure and record the same in respective log of equipment’s.

6.4 Cleaning:

- 6.4.1 Ensure that the Pass Box are Switched “OFF”.
- 6.4.2 Clean the pass box from outside & inner side by using lint free cloth & moping with 70% IPA as per given details in **Annexure –I & Annexure –IVIII.**
- 6.4.3 Switch “ON” the main switch.
- 6.4.4 **Cleaning & DP monitoring Frequency:** Daily once / whenever required / after Preventive Maintenance activity/after rectification of breakdown.

6.5 Filter Cleaning:

- 6.5.1 All filters shall be cleaned in filter washing area as per **SOP.**
- 6.5.2 All filters shall be cleaned in filter washing area
- 6.5.3 Store person intimate to engineering department for filter cleaning as per **SOP.**
- 6.5.4 Store person enter the filter remove & install operation detail in **Annexure.**
- 6.5.5 Clean the pass box after install the cleaned filter and enter in log book.
- 6.5.6 **Frequency of filter cleaning:- Monthly ± 7 days** or whenever required.



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7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Dynamic Pass Box Log for I & Q Block	
Annexure-I	Schedule of UV light replacement Record	
Annexure-III	Status Label of UV light replacement	
Annexure-IV	Dynamic Pass Box Log for L & Q Block	

ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

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

9.0 REFERENCES:

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-I DYNAMIC PASS BOX CLEANING & USAGE LOG

Equipment ID:

Block:

Section:

Location:

Frequency of Cleaning & DP:

Daily once / whenever required/ after Preventive maintenance activity/after rectification of breakdown.

S.No.	Date	Product Name & Activity@	Batch No	Start Time	End Time	Pressure Diff. HEPA filter (10-20 mm of water)	UV Light Status (Ok/ Not Ok)	Done By	Checked By Sign & Date

Remark: @Activity means DP monitoring, Cleaning, Preventive maintenance & Breakdown related activities.

**Reviewed by QA
Sign & Date:**



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ANNEXURE-III STATUS LABEL OF UV LIGHT REPLACEMENT

STATUS LABEL OF UV LIGHT REPLACEMENT	
Equipment Name	
Equipment ID	
UV light installation date	
UV light replacement due date	
Done By (Sign. & Date)	
Checked By (Sign. & Date)	



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ANNEXURE-IV DYNAMIC PASS BOX CLEANING & USAGE LOG

Equipment ID: _____ **Block:** _____ **Section:** _____ **Location:** _____

Frequency of Cleaning & DP:

Daily once / whenever required/ after Preventive maintenance activity/after rectification of breakdown.

S.No.	Date	Product Name & Activity@	Batch No	Start Time	End Time	Pressure Diff. HEPA filter (5-15 mm of water)	Pressure Diff. Pre filter (0.6-4 mm of water)	UV Light Status (Ok/ Not Ok)	Done By	Checked By Sign & Date

Remark: @ Activity means DP monitoring, Cleaning, Preventive maintenance & Breakdown related activities.

Sign & Date: