



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Operation And Cleaning Of Dynamic Pass Box

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
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1.0 OBJECTIVE:

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

2.0 SCOPE:

This SOP is applicable for Operation and Cleaning of Dynamic Pass Box provided in Production Department.

3.0 RESPONSIBILITY:

Officer / Executive Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

HEPA	High Efficiency Particulate Air
IPA	Iso Propyl Alcohol
LAF	Laminar Air Flow
Ltd.	Limited
mm	Milli Meter
No.	Number
Pvt.	Private
SLS	Sodium Lauryl Sulphate
SOP	Standard Operating Procedure
UV	Ultra Violet
%	Percent

6.0 PROCEDURE:

6.1 INSTRUCTION:

6.1.1 Blower of every Dynamic Pass Box shall be kept “ON” always except Cleaning, Breakdown & Preventive maintenance.

6.1.2 UV light of every pass box should be “ON” during the operational shift.

6.2 OPERATION:

6.2.1 Switch “ON” the Main Switch.

6.2.2 Check the Pressure drop across the HEPA Filter and ensure that it should be within 05 – 15 mm of water on Magnehelic Gauge.

6.2.3 Check the Pressure drop across the PRE Filter and ensure that it should be within 0.6 – 4 mm of water on Magnehelic Gauge.

6.2.4 Open the door and Ensure that UV Lights function is OK.



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- 6.2.5** If any abnormal sound is observed from the unit, the unit must be checked for its wear and tear.
- 6.2.6** Sanitize external surface of all the containers or objects to be transferred through this Dynamic Pass Box with 70 % IPA Solution.
- 6.2.7** Before transferring the material check and ensure that Inner Side Door of Dynamic Pass Box closed.
- 6.2.8** Open the door of the Dynamic Pass Box and transfer all the Sanitized Containers / Objects inside the Dynamic Pass Box and close the door.
- 6.2.9** For ensuring the working of blower checks the pressure differential in Magnehelic gauge.
- 6.2.10** Let the container remain inside the Dynamic Pass Box for 20 minutes. If any material is being transferred between two same grade area or from higher grade area to lower grade area then no need to hold the material inside the pass box.
- 6.2.11** Material transfer from one grade to another grade should be as given in below table:

Equipment ID	From	To	UV Expose time	Reason
	RM day store	D grade corridor	5 min.	Movement in same grade
	Granule feeding	D grade corridor	5 min.	Movement in same grade
	Scrap out	D grade corridor	5 min.	Movement in same grade
	Disinfectant prep.	D grade corridor	5 min.	Movement in same grade
	Manufacturing -01	D grade corridor	20 min.	#Movement D to C grade
	Manufacturing -02	D grade corridor	20 min.	#Movement D to C grade
	Garment Washing	D grade corridor	5 min.	Movement in same grade
	Entry A/L-02	C grade corridor	5 min.	Movement in same grade
	Garment Washing	UPR	5 min.	Movement in same grade
	UPR	D grade corridor	5 min.	Movement in same grade
	UPR	C grade corridor	20 min	Movement D to C grade
	Scrap out	C grade corridor	NA	Movement C to D grade

Remark: # Handling of unsterile material

- 6.2.12** Push the buzzer switch to indicate the person working another side of dynamic pass box to receive the material.
- 6.2.13** Open the inner Side Door of Dynamic Pass Box and take out all the containers from Dynamic Pass Box in to the Area and close the inner side door of the Dynamic Pass Box.

6.3 CLEANING:



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- 6.3.1 Open the inside door of Dynamic Pass Box.
- 6.3.2 Clean the inner side as well as outer side of cabinet with cleans & lint free cloth.
- 6.3.3 Sanitize its inner surface using disinfectant solution scheduled for the day and dry it with Lint Free Cloth.
- 6.3.4 Sanitize the outer surface of Dynamic Pass Box and close the Non-Sterile side door.
- 6.3.5 Switch “ON” the main switch.
- 6.3.6 Switch “ON” the UV light and let it being operation for 20 minutes.
- 6.3.7 Check the Pressure drop across the HEPA Filter and ensure that it should be within 05 – 15 mm of water on Magnehelic Gauge.
- 6.3.8 Check the Pressure drop across the PRE Filter and ensure that it should be within 0.6 – 4 mm of water on Magnehelic Gauge.
- 6.3.9 Record the cleaning details in **Annexure-I** and **Annexure-II**.
- 6.3.10 **Cleaning Frequency : Daily**

6.4 CLEANING OF GRILL AND PRE-FILTERS :

- 6.4.1 Switch ‘Off’ the LAF unit.
- 6.4.2 Take out the outer perforated frame and send it to washing area for cleaning.
- 6.4.3 Take out the pre-filters of LAF, place in a polybag and Label it with to be cleaned status label and transfer it to designated washing area.
- 6.4.4 Clean it with purified water followed by filtered air.
- 6.4.5 Spray filtered 70% IPA solution on it.
- 6.4.6 After Cleaning the frame and Pre -Filters will be taken in the respective area.
- 6.4.7 Whole unit of LAF should be cleaned / mopped with 70% IPA solution.
- 6.4.8 Spray filtered 70% IPA solution all over the filters and cover frame.
- 6.4.9 Affix the Pre - Filter and cover frame at its specified place.



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6.4.10 Grill & Pre-Filter Cleaning Record Frequency: Monthly.

6.5 Monitoring & replacement of UV lamp (As per manufacturer certificate) shall be done and record in “UV Light Usage and Replacement Record log book.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	UV Light Usage And Replacement Record	
Annexure-II	Operation & Cleaning Record Of Dynamic Pass Box	

ENCLOSURES: SOP Training Record.

8.0 DISTRIBUTION:

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



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ANNEXURE-I UV LIGHT USAGE AND REPLACEMENT RECORD

Block : **Department** :
Location : **Month** :
EQ. ID NO. : **Year** :
Frequency: Daily

Date	Shift	Pre Reading	Total Reading	Burning Hours	Replace ment date	Done by Date & Sign	Checked By Sign & Date	Remark

Note: UV Light change as per certificate provide by manufacture

