



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

**Title:** Transfer of Sterile Raw Material & Environmental Monitoring Kit Container in Aseptic Area Through Dynamic Pass Box

<b>SOP No.:</b>		<b>Department:</b>	Production	
		<b>Effective Date:</b>		
<b>Revision No.:</b>	00	<b>Revision Date:</b>		
<b>Supersede Revision No.:</b>	Nil	<b>Page No.:</b>	1 of 4	

### 1.0 OBJECTIVE:

To lay down a procedure for Transfer of Sterile Raw Material Container & Environmental Monitoring Kit Container in Aseptic Area through Dynamic Pass Box.

### 2.0 SCOPE :

This SOP is applicable for Transfer of Sterile Raw Material Container & Environmental Monitoring Kit Container in Aseptic Area through Dynamic Pass Box.

### 3.0 RESPONSIBILITY :

Officer / Executive- Production & QC- Microbiology

### 4.0 ACCOUNTABILITY :

Head Production

### 5.0 ABBREVIATIONS :

IPA	Isopropyl Alcohol
Ltd.	Limited
No.	Number
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure
UV	Ultra Violet

### 6.0 PROCEDURE:

#### 6.1 PRECAUTIONS:

**6.1.1** Use the solution within 24 hours of Preparation.

**6.1.2** Balance quantity of disinfectant should be discarded daily.

#### 6.2 TRANSFER OF STERILE RAW MATERIAL CONTAINER :

**6.2.1** Production person shall check and verify the dispensed Raw material container in store before its transfer to Aseptic area.

**6.2.2** Production person shall physically observe the Raw Material container for its intactness and cleanliness.

**6.2.3** Check & ensure that each container has “**Raw Material Identification Slip**”.

**6.2.4** Verify that dispensed material quantity is as per Material Requisition Slip & BMR (Batch Manufacturing Record).

**6.2.5** Verify the AR. No. mentioned on issue slip with mentioned on the dispensed item.



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- 6.2.6 Check the weight of each container and record its gross weight at specified column in BMR.
- 6.2.7 Dispensed material shall be transferred through lift to production area by clean S.S.Cage trolley.
- 6.2.8 Sanitize the outside surface of containers by mopping with 5% Virosil / Silvicide solution and keep it for 20 minutes inside Dynamic Pass Box under UV light and transfer it into Aseptic area.
- 6.2.9 Unload the containers by opening the Dynamic Pass Box cabinet from Aseptic area side.
- 6.2.10 Switch 'OFF' the UV light of Dynamic Pass Box.
- 6.2.11 Clean the Dynamic Pass Box with mopping pad by using 70% IPA solution.
- 6.2.12 Proceed for further processing by transferring all the material in respective processing area.

### 6.3 TRANSFER OF ENVIRONMENTAL MONITORING KIT CONTAINER:

- 6.3.1 Concern Microbiologist shall bring environmental monitoring kit from Microbiology lab to production area for Microbiological Environmental Monitoring.
  - 6.3.2 Bring to SS container to material entry room of production area.
  - 6.3.3 Sanitize the outside surface of containers by mopping with 5% Virosil / Silvicide solution and keep it for 20 minutes inside Dynamic Pass Box under UV light and transfer it into Aseptic area.
  - 6.3.4 Unload the containers by opening the Dynamic Pass Box cabinet from Aseptic area side.
  - 6.3.5 Switch 'OFF' the UV light of Dynamic Pass Box.
  - 6.3.6 Clean the Dynamic Pass Box with mopping pad by using 70% IPA solution and allow it to dry.
  - 6.3.7 Proceed for environmental monitoring as per respective SOP by transferring the material in respective area.
- 6.4 Record the usages details in **Annexure-I**, Titled "**Dynamic Pass Box Utilization Record**" of SOP.
- 6.5 Record the Preparation & Destruction record of disinfectant solution as per **Annexure-I**, Titled "**Issuance, Usage and Destruction Record of 5% Virosil / Silvicide Solution**".

### 7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Issuance, Usage and Destruction Record of 5% Virosil / Silvicide Solution	



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**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:

SOP, Titled “Operation and Cleaning of Dynamic Pass Box”.

### 10.0 REVISION HISTORY:

#### CHANGE HISTORY LOG

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

