



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

**Title:** Dispensed Material Inward and Outward Movement

<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 describe a procedure for Dispensed material inward and outward movement in dispensing area to RM Day store area and movement in manufacturing area

### 2.0 SCOPE:

The SOP is applicable for Dispensed material inward and outward movement in dispensing area to RM Day store area and movement in manufacturing area in production department.

### 3.0 RESPONSIBILITY:

Officer / Executive – Production.

### 4.0 ACCOUNTABILITY:

Head – Production

### 5.0 ABBREVIATIONS:

Not Applicable

### 6.0 PROCEDURE:

#### 6.1 RECEIVING AND STORAGE OF DISPENSED RAW MATERIALS:

**6.1.1** After dispensing activity the dispensed raw materials transferred to RM Day store area through material lift and record the details in “**Dispensed Materials Inward and Outward Movement**” **Annexure -I**

**6.1.2** In case of Three specie /DPI dispensed raw materials transferred to RM Days store area through material lift and followed by respective static pass box and record the details in “**Dispensed Materials Inward and Outward Movement**” **Annexure-I**

**6.1.3** Store the dispensed material with appropriate labels till they are taken up manufacturing activity.

**6.1.4** During storage container should be closed with lid to avoid the mix-ups.

**6.1.5** Monitor the temperature during material storage as per respective SOP and record details in “Temperature and Relative humidity Record “.

#### 6.2 TRANSFER OF DISPENSED RAW MATERIALS TO MANUFACTURING AREA:

**6.2.1** Production personnel should check and ensure the dispensed raw material with BMR and transfer to manufacturing dynamic pass box area through static pass box and record the details in “**Dispensed Materials Inward and Outward Movement**” **Annexure -1**

**6.2.2** While transferring ensure the dispensed containers are closed and transferring trolley should be cleaned and labeled with product name and batch details.



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**6.2.3** Transfer the dispensed materials from manufacturing dynamic pass box area to batch manufacturing area through dynamic pass box

**6.2.4** While transferring ensures the through dynamic pass box cleanliness and DP status.

**6.2.5** In case of cold storage materials (product maintained 2 to 8 degree) stored at deep freezer after dispensing and then transferred to manufacturing area before addition of the manufacturing activity and record the details in **“Dispensed Materials Inward and Outward Movement” Annexure -1**

### **6.3 TRANSFER OF DISPENSED STERILE RAW MATERIALS (DPI) TO ASEPTIC FILLING AREA:**

**6.3.1** Production personnel should check and ensure the dispensed sterile raw material with BMR and transfer to Aseptic filling dynamic pass box area through static pass box and record the details in **“Dispensed Materials Inward and Outward Movement” Annexure -1**

**6.3.2** While transferring ensure the dispensed containers are closed and transferring trolley should be cleaned and labeled with product name and batch details.

**6.3.3** Transfer the dispensed sterile materials from aseptic filling dynamic pass box area to Aseptic filling area through dynamic pass box

**6.3.4** While transferring clean the dynamic pass box surface with 70% IPA.

**6.3.5** Ensure the DP status of the dynamic pass box as per respective standard operating procedure.

**6.3.6** Sanitize the outer surface of the dispensed sterile container with 5% silivicide

**6.3.7** Store the dispensed sterile material with appropriate labels till they are taken up filling activity.

**Note:**

*Sterile container should be examined visually while store in to the LAF.*

*Check intactness of the dispensed sterile materials*

*Damaged container segregated from other material and kept aside.*

**6.4** Materials inward and out ward movement discrepancy addressed through handling of incident **SOP.**

### **7.0 ANNEXURES:**

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure – I	Dispensed Materials Inward and Outward Movement	

**ENCLOSURES:** SOP Training Record



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### 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

