



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

**Title:** Storage of Filled/Sealed Containers of Large Volume Parenteral Products

<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 2

### 1.0 OBJECTIVE:

To lay down a Procedure for Storage of Filled/Sealed Containers of Large Volume Parenteral Products.

### 2.0 SCOPE:

This SOP is applicable for storage of filled/sealed containers of Large Volume Parenteral products in Production Area.

### 3.0 RESPONSIBILITY:

Officer/Executive Production

### 4.0 ACCOUNTABILITY:

Head Production

### 5.0 ABBRIVATION:

BPCR	Batch Production & Control Record
CB	Corrugated Box
Ltd	Limited
No.	Number
Pvt.	Private
QA	Quality Assurance
SHWSS	Super-Heated Water Spray Sterilizer
SOP	Standard Operating Procedure

### 6.0 PROCEDURE:

#### 6.1 STORAGE OF FILLED/SEALED CONTAINERS OF LARGE VOLUME PARENTERAL PRODUCTS:

- 6.1.1 After terminal sterilization open the door of SHWSS and unload the trolley one by one and arrange these trolleys in the unloading area.
- 6.1.2 After unloading of sterilized bottles from SHWSS, if packing line is not ready for packing, then unload these bottles from the trolley.
- 6.1.3 Unload the sterilized bottles into plastic crate/C box after sterilization and close the C box/ crate.
- 6.1.4 Now arrange these c box and Crate on the clean pellet.
- 6.1.5 Arrange the C box/ crate in a manner, i.e. 8 x 6 layers in a single pellet.



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**6.1.6** Affix/update the status label on each crate/C box.

**6.1.7** As the packing line is ready for packing, transfer this bottle along with C box/Crate into packing area for further processing.

### 7.0 ANNEXURES:

Not Applicable

**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