



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production (External Preparation)	<b>SOP No.:</b>
<b>Title:</b> Cleaning & Operation of Semi Automatic Crimping Machine	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

### 1.0 OBJECTIVE:

To lay down a Procedure for Cleaning & Operation of Semi Automatic Crimping Machine.

### 2.0 SCOPE:

This SOP is Applicable to Cleaning & Operation of Semi Automatic Crimping Machine in Ointment Section.

### 3.0 RESPONSIBILITY:

Officer/Executive – Production

### 4.0 ACCOUNTABILITY:

Head Production

### 5.0 ABBREVIATIONS:

No.	Number
IPA	Iso Propl Alcohol
SOP	Standard Operating Procedure
PLC	Programmable logic control
QC	Quality control

### 6.0 PROCEDURE:

#### 6.1 CLEANING:

6.1.1 The status on status board as under cleaning.

6.1.2 Check visually for remnant of previous batch, remove from the Semi Automatic Crimping Machine and from the area.

6.1.3 Also check below the Semi Automatic Crimping Machine.

6.1.4 Clean the Semi Automatic Crimping Machine with clean and dry mop.

6.1.5 Use 70% IPA to clean stains, if require.

6.1.6 Clean the waste bin of the area.

6.1.7 Write the “Cleaned” status on the Status Board.

6.1.8 Record the cleaning details in Equipment Log and area Cleaning Record.

#### 6.2 OPERATION:

6.2.1 Unlock knob and lift support block fully up with the help of the handwheel.

6.2.2 With the help of spanner (10-11), unscrew the V-Block and take it behind.

6.2.3 Now connect the Air supply to the FRL Unit with aproiate pressure of air. Make on/off valve



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ON.

**6.2.4** Take an empty Bottle, place it hanging on the collet, keep the foot pedal pressed and lower the support block till the Bottle touches the base plate. The Bottle should be just tight.

**6.2.5** Check and feel by turning Bottle by left hand with little pressure, Bottle should not rotate.

**6.2.6** Then lock the knob at that position and take the V-Block in front so that it just touches the Bottle and tighten the screws.

**6.2.7** Once its done, **RELEASE THE FOOT PEDAL.**

**6.2.8** Place Bottle with product and Pump on baseplate touching the V-Block.

**6.2.9** And press foot pedal and leave.

**6.2.10** Now the crimped Bottle is obtained.

**6.2.11** If crimp is not ok, set machine for crimp depth and crimp diameter.

### **6.2.12 Adjustments:**

#### **6.2.12.1 Crimp Depth Adjustment:**

**6.2.12.1.1** Insert 6 mm Allen key from bottom of collet.

**6.2.12.1.2** Rotate Allen key clockwise to decrease depth and anti-clockwise to increase.

**6.2.12.1.3** Crimp bottle and observe crimping.

#### **6.2.12.2 Crimp Diameter Adjustment:**

**6.2.12.2.1** Loosen the lock nut.

**6.2.12.2.2** Rotate Diameter adjuster Anti-clockwise to decrease diameter and Clockwise to increase the diameter.

**6.2.12.2.3** Lock the lock nut and check crimping.

#### **6.2.12.3 Collet Replacement:**

**6.2.12.3.1** Loosen locknut and remove Diameter Adjuster.

**6.2.12.3.2** Remove the cross pin by Mallet.

**6.2.12.3.3** Remove collet and Spring.

**6.2.12.3.4** Replace the Damaged collet and spring with New ones.

**6.2.12.3.5** Align the holes and insert pin.



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**6.2.12.3.6** Put back the Diameter adjuster, make setting, tighten the locknut.

### 7.0 ANNEXURES:

Not Applicable

**ENCLOSURE:** 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