



## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production (External Preparation)	<b>SOP No.:</b>
<b>Title:</b> Cleaning & Operation of Auto-Cartoning 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 Auto- Cartoning Machine.

### 2.0 SCOPE:

This SOP is applicable to Cleaning & Operation of Cartoning Machine in Ointment section.

### 3.0 RESPONSIBILITY:

Production Officer/Executive

### 4.0 ACCOUNTABILITY:

Head Production

### 5.0 ABBREVIATIONS:

BPCR	Batch Production and Control Record
I/O	Input and Output
IPQA	In-Process Quality Assurance
M/C	Machine
No.	Number
PLC	Programmable logic Controller
SOP	Standard Operating Procedure

### 6.0 PROCEDURE:

#### 6.1 CLEANING :

**6.1.1** Put the status on status board as under cleaning.

**6.1.2** Check visually for Remnant of Previous Batch, remove if found any from the Cartoning Machine and from the area.

**6.1.3** Also check below the Cartoning Machine.

**6.1.4** Clean the conveyor belt 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 GENERAL REQUIREMENT:

**6.2.1** Check the cleanliness of Auto- Cartoning Machine.

**6.2.2** Check the "CLEANED" Status label on Cartoning Machine.

**6.2.3** Ensure that the Environmental Conditions are as per specification in BPCR and enter the Same into BPCR as well as in Environmental Monitoring Record.



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**6.2.4** Remove the Cleaned status label from equipment and place an Equipment status label on it.

**6.2.5** Take Line Clearance from IPQA.

### **6.3 OPERATION:**

#### **6.3.1 ELECTRICAL PANEL:**

**6.3.1.1** Run the machine using the 'START' and 'STOP' buttons to check that the machine functions are operation correctly.

**6.3.1.2** Check that the start and stop functions, emergency stop and door security switches are operating correctly. The machine can only start when doors and covers are closed.

**6.3.1.3** Run the machine slowly with tubes and product to check that all the operational functions are working correctly.

**6.3.1.4** The machine is now ready for production.

#### **6.3.2 Operation Sequence:**

**6.3.2.1** Start air supply up to 3-4kg/cm<sup>2</sup>, cassette on & registration on.

**6.3.2.2** If one of the functions were not start or out of order, then the machine wouldn't ready to run.

#### **6.3.3 Product conveyor (Inlet Conveyor):**

**6.3.3.1** Consist of chain conveyor covered with nylon & aluminum pockets for proper guiding of product during insertion process.

#### **6.3.4 Leaflet Insertion Device:**

**6.3.4.1** Its device where pre folded leaflets are loaded into a magazine & there after travel along with product with the help of chain & get inserted into carton.

#### **6.3.5 Product Pusher Assembly:**

**6.3.5.1** Number of pusher guided with the help of cam insert the product into carton along with leaflet.

#### **6.3.6 Carton Magazine Assembly:**

**6.3.6.1** In this assembly cartons are loaded in unfolded form, there after cartons are formed and transferred to the carton chain for further process and the change over setting for various carton sizes is done without any tool (i.e. Tool less change over setting provision).

#### **6.3.7 Carton Chain & Flap Folding Assembly:**

**6.3.7.1** In this assembly after forming is further taken to the next station with the help of clit chain and the side flaps are folded and guided for further process and at the same time on one of the



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major flap of carton printing or coding is done with the help of rubber stereo or metal engraving unit.

### 6.3.8 Tuck-In Assembly:

**6.3.8.1** Carton along with the product in it is finally enclosed in this assembly where the side flaps are either closed by just pressing the side flaps.

### 6.3.9 Carton Discharge Assembly:

**6.3.9.1** In this assembly the final enclosed carton is transferred to next machine or collected in a bin.

### 6.3.10 Interconnection Assembly:

**6.3.10.1** This Assembly mainly consists of conveyor and linkup assembly, which is used to interconnect the two machines for automatic feeding of product from inlet machine to the product conveyor of cartoning machine.

## 6.4 PROCESS:

Filled tube form Tube Filling Machine are been transferred to the product conveyor with the help of interconnection assembly then after it the tubes gets dropped into product conveyor which is driven with the help of drive of machine after the tube gets inserted in the product conveyor the leaflet assembly takes out leaflets and transfer it to the chain (leaflet Chain) which travels parallel with tube in product conveyor, When the tube is passes the leaflet station a sensor sense the presence of product in pocket of conveyor then the cartons is drawn from magazine assembly and carried to the carton chain, Once all the products, carton & leaflet are sensed, product pusher does the loading. If for any reason carton or leaflet is not available, the loading system will bypass the said products & machine stops.

When the tube and leaflet reach at pushing stations multiple pushers' starts pushing the tube in the direction of carton and when it reaches to its end limit the tube and leaflet are inserted inside the carton with help of pushers further the side flaps of carton are folded with the help of folders and guides then the carton chain take the cartons to the gluing station (Tuck in station) where the glue is applied to enclose the flaps of cartons (or Flaps are pushed inside during tuck in cartons) after which the carton chain push the carton into ejection assembly where the two belt conveyors takes the carton to the end of machine and ejects the cartons.

## 6.5 SAFETY PRECAUTION:

**6.5.1** In case of danger to people or risk of damage to the machine the **EMERGENCY** stop button must be pushed.

**6.5.2** When you have finished operating the machine, shut off electrical power supply.

## 7.0 ANNEXURES:

Not Applicable



# PHARMA DEVILS

PRODUCTION DEPARTMENT

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**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:

Party manuals

### 10.0 REVISION HISTORY:

#### CHANGE HISTORY LOG

Revision No.	Change control No.	Details of Changes	Reason for Change	Effective Date	Updated By