STANDARD OPERATING PROCEDURE

Department: Production	**SOP No.:**
Title: Operation and Cleaning of Sticker Labeling Machine	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure for Operation and Cleaning of Sticker Labeling Machine.

2.0 SCOPE:

This SOP is applicable for Operation and Cleaning of Sticker Labeling Machine in Production Area of Ampoules and Vial Line at ……………..

3.0 RESPONSIBILITY:

Officer/Executive Production

4.0 ACCOUNTABILITY:

Head Production

5.0 DEFINITIONS:

Not Applicable

6.0 PROCEDURE:

6.1 Operation:

6.1.1 Before operation take the area line clearance from QA personnel.

6.1.2 Bring the dispensed labels in the packing area.

6.1.3 Switch "ON" the mains power Button.

6.1.4 Before start of operation, run the empty machine for at least 2 minutes.

6.1.5 Perform Challenge test of sensors before start of operation and after any break-down of machine.

6.1.6 Record the details of sensors challenge test in **Annexure-I**

6.1.7 Load the label roll in Dancing roll.

6.1.8 Adjust peel off the paper about 5 to 10 mm from the scraper blade by rotating the pinch roller manually.

STANDARD OPERATING PROCEDURE

Department: Production	**SOP No.:**
Title: Operation and Cleaning of Sticker Labeling Machine	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

6.1.9 Adjust the Label Sensor's point mark between two labels gap.

6.1.10 After adjusting the Sensor's point between two labels gap, press Auto Set button given on the Sensor & wait for three seconds.

6.1.11 The green light given on the Sensor's will start blinking., move the Label forward, reverse and adjust the Label Sensor's point mark on the label and press Auto Set button again and light will stop blinking.

6.1.12 Follow the same procedure to get the best performance of the machine every time while changeover the size.

6.1.13 Adjust the guide Rails according to container size such as, the container should move freely on to the conveyor.

6.1.14 Press Pressure Plate against container in such a way that the container is under slight pressure. Re-tighten the Knob.

6.1.15 Put some containers on conveyor and checks the sticking of labels there on.

6.1.16 Adjust the product sensor forward or reverse if any crease of labels after pasting is observed.

6.1.17 To change the label application height on the container, move the hand wheel given below the top plate clock-wise & anti clock-wise for up/down.

6.1.18 Re- tightens the bolt of hand wheel.

6.1.19 Enter the user details and password to open the system.

6.1.20 To set the printing details open the message.

6.1.21 Following display on the screen, press the job icon.

6.1.22 After press the job icon, following display on the screen then type and set Batch No., Mfg. Date, EXP. Date, in the system from the BPR and MRP from MRP file then press ok.

6.1.23 After setting the printing details check details with BPR after zooming it.

6.1.24 On main of the HMI by pressing start button.

6.1.25 Following display on screen for User login and Password.

6.1.26 Enter the user name, and enter the Pass word. Now Press the login, on following display:

6.1.27 HMI show following display, press the MAIN icon.

STANDARD OPERATING PROCEDURE

Department: Production	**SOP No.:**
Title: Operation and Cleaning of Sticker Labeling Machine	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

6.1.28 HMI show following display for running machine press the label off and conveyor icon to start the machine.

6.1.29 Start the machine and get first two prints on the label in order to get QA approval.

6.1.30 During labeling Operation of Vials/Ampoules visual inspector continuously verify the Vials/Ampoules coding.

6.1.31 Without coding Vials/Ampoules identified by visual inspector shall be kept in rejection box for relabeling.

6.1.32 The visual inspector shall be rotated after every two hours.

6.1.33 Record the details of verification of coded Vials/Ampoules in **Annexure-II**

6.1.34 De label the all improper labeled rejected Vials/Ampoules, manually and do re label.

6.1.35 After completion of labeling operation stop the machine by pressing STOP option and shutdown the printer.

6.2 **CLEANING:**

6.2.1 Switch **"OFF"** the electric supply of the machine.

6.2.2 Remove guard and pressing belt.

6.2.3 Clean the machine and its parts with 70% IPA solution.

6.2.4 Clean the surrounding area of the machine with compressed air gun.

6.2.5 Fix the guard and pressing belt at its specified place.

6.2.6 If machine is not used within 24 hrs, re-clean it before its operation.

6.2.7 Record the operation details in Format Titled **"Equipment Log"** of SOP.

6.2.8 **Frequency:** Carry out the cleaning process everyday before startup of a shift and at the end of operation.

7.0 **ABBREVIATIONS:**

SOP   Standard Operation Procedure

QA   Quality Assurance

	PHARMA DEVILS	
	PRODUCTION DEPARTMENT	

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Sticker Labeling Machine	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Ltd.	Limited
No.	Number
Mfg.	Manufacturing
Exp	Expiry
BPR	Batch Packing Record

8.0   ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Sensor Challenge Test Record	
Annexure-II	Verification of coded Vials/Ampoules	

9.0   DISTRIBUTION:

- Master Copy   Quality Assurance Department
- Controlled Copy No. 01   Production Department

10.0   REFERENCES:

SOP Titled "**Equipment Log**".

11.0   REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		

STANDARD OPERATING PROCEDURE

Department: Production	**SOP No.:**
Title: Operation and Cleaning of Sticker Labeling Machine	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE-I

SENSOR CHALLENGE TEST RECORD

Frequency: Before Start of Operation and After Machine Break-Down

Date	Product Name	Batch No.	Sensor Details	Status (Ok / Not Ok)	Done By Sign & Date	Checked By Sign & Date	Verified By Sign & Date	Remarks
			Coding Sensor					
			Label Sensor					
			Product Sensor					
			Rejection Box Sensor					
			Door Interlocking Sensor					

STANDARD OPERATING PROCEDURE

Department: Production	
TITLE: Operation and Cleaning of Sticker Labeling Machine	

SOP No.		**Revision No.**	
Effective Date		**Supersedes No.**	
Review Date		**Page No.**	6 of 6

ANNEXURE-II
Verification of coded Vials/Ampoules

S.No	Date	Time		Product Name	Batch No.	No. of Vials/Ampoules Inspected	Rejected Qty.	Inspected By Sign & Date	Checked By Sign & Date	Verified By Sign & Date	Remarks