



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning and Operation of Sticker Labeling machine with Condot Printer	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

**Vernacular SOP:** No

### 1.0 OBJECTIVE:

- 1.1. To lay down a procedure for Cleaning and Operation of Sticker Labeling Machine with Domino Printer.

### 2.0 SCOPE:

- 2.1. This procedure is applicable to the cleaning and operation of Sticker Labeling Machine with Domino printer with in Production area.

### 3.0 RESPONSIBILITY:

- 3.1. Technical Associate : Cleaning and Operation
- 3.2. Officer/ Executive Production : Supervision
- 3.3. Head Production : SOP Compliance
- 3.4. IPQA : Line Clearance

### 4.0 DEFINITION(S):

- 4.1. NA

### 5.0 PROCEDURE:

#### 5.1. CLEANING

- 5.1.1. Remove all material of previous product/batch from the machine.
- 5.1.2. Remove the "UNDER PROCESS" status label and affix "TO BE CLEANED" status label on machine with signature of production officer.
- 5.1.3. Remove all over printed Sticker labels and destroy them after reconciliation as per respective BPR.
- 5.1.4. Remove the release paper roll from the unwinding roller
- 5.1.5. Clean the unwinding rollers with 70% v/v IPA solution and with dry lint free cloth.
- 5.1.6. Clean all the sticky material from the label release plate with 70% v/v IPA solution.
- 5.1.7. Clean the sensor with dry cloth.
- 5.1.8. Clean the conveyor belt, bottle guide with wet cloth followed by lint free dry cloth.
- 5.1.9. Clean the wrapper round belt & bottle guide (rubber) with wet lint free cloth and remove all the sticky materials from there gently.
- 5.1.10. Wipe the SS machine covers with wet cloth followed by dry cloth.

#### 5.2. Cleaning for printing head

- 5.2.1. Remove the ink cartridge from the printing unit.
- 5.2.2. Clean the head of the ink cartridge with the help of lint free cloth.
- 5.2.3. Store the ink cartridge in to the poly bag.



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- 5.2.4. Frequency: At the end of process
- 5.2.5. Status Labeling: - Affix "CLEANED" label on the machine as per SOP.
- 5.2.6. Record the details of cleaning of sticker labeling machine in equipment usage and cleaning log sheet as per SOP.
- 5.3. **Machine set up and Operation**
- 5.3.1. Ensure that sticker labeling machine is cleaned.
- 5.3.2. Install the label roll on the roll stand and set the roll label on the machine.
- 5.3.3. Measure the length of single label by using a cm scale or by using the label length option on the PLC screen and press enter, the machine automatically calculate the length of the label. Then measure the pre dispensing Length i.e the distance between two consecutive labels.
- 5.3.4. Adjust the pre dispensing length between 5-12 mm.
- 5.3.5. Bottle separator separate one bottle from other end and maintain the distance between the two consecutive bottles.
- 5.3.6. Bottle guide direct the bottle in a single direction
- 5.3.7. Adjust the height of the label by adjusting the roller and guides.
- 5.3.8. Adjust the thickness of sticker roll ribbon from dancing roll spring and from stainless steel tension strip.
- 5.3.9. PLC programmer and function:

<b>NEXT</b>	<b>▲</b>	<b>TOG</b>	<b>F1</b>
<b>◀</b>	<b>ENT</b>	<b>▶</b>	<b>ESC</b>
<b>PREV</b>	<b>▼</b>	<b>MAN</b>	
<b>START</b>	<b>STOP</b>		<b>RUN</b>

- 5.3.10. **ESC: Release**  
**RUN:** For Machine Run  
**START:** For Conveyor  
**▲:** For increasing  
**▼:** For decreasing  
**◀:** For changing on left side



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►: For changing on right side

**MAN:** Not applicable

**F1:** **Not applicable**

5.3.11. **ENT:**

5.3.11.1. Label speed – 5 to 20 meter/minute.

5.3.11.2. Label Length –It is measure as total length + gap between two label + 2mm.

5.3.11.3. Pre-dispensing – Normally 10mm.

5.3.11.4. Printer 1 time – Not applicable.

5.3.11.5. Printer2 time – Not applicable.

5.3.11.6. Label sensor – At 00

5.3.11.7. Reset label – ESC –then ENT –Reset total label- “N”-then press: TOG” key and press –ENT –then ESC – then-RUN –it observe 0.0

5.4. **Setup for condor Printer:**

5.4.1. Insert the data card in to the card reader and attach the data card to the computer system.

5.4.2. Feed the coding programmed as per Below instruction (Message editing) –

5.4.3. Select HP51645A head type select TCU option selects 12.7 mm in Head engine type Click on Add followed by Ok A area for the new message appear on the screen.

5.4.4. Select ABCD option from the Icon Make a Text line area & Type the message line by line in the Text column giving on the top of the Icon by pressing enter key.

5.4.5. Save the message in the TCU folder situated in OBJ INK draw folder, which is situated in program file of c:/ disk.

5.4.6. Move the message to the Data card from the system by using the yellow colored folder icon situated at the top of the icons.

5.4.7. Select F:/ drive & type the message name such as TCU-1 (1 TO 10 ONLY) – click on save.

5.4.8. Cut off the link of the data cable from the computer system and remove the data card from the card Reader.

5.4.9. Insert the data card in to the setup box and select the message no form the message selecting knob situated on the lower side of the machine, switch ON the machine and press start button situated on the setup box.

5.4.10. Turn the knob towards ON, press the ESC button then press RUN after pressing the RUN machine will start.

5.4.11. After the completion of operation, Switch ‘OFF’ electric supply.

5.4.12. Affix “TO BE CLEANED” label on the machine as per SOP.

5.4.13. Record the details of operation of sticker labeling machine in equipment usage log sheet as per SOP.



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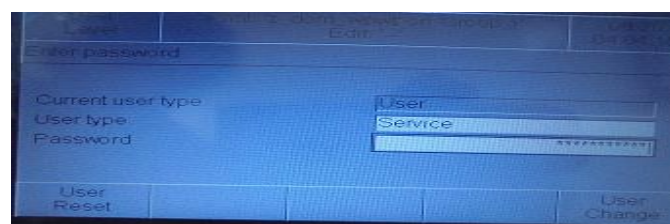
### 5.5. Procedure for creating the label in Domino Printer:

5.5.1. Switch "ON" the power supply of the printer controller unit screen will display as;

S.No.	Parameter name	Description
1.	Message height	Height of each head is 12.7 mm
2.	Message width	Displays width of canvas (width can be changed as per requirement)
3.	Forward margin	Displays margin to be kept after starting of text.
4.	End margin	Displays margin to be kept after ending of text.
5.	Print start mode	Displays PRINT TYPE i.e. ENCODER base or sensor base (External)
6.	Print speed mode	Displays PRINT speed i.e. ENCODER base or sensor base (External)
7.	Production speed	It is the Velocity of the print (no need to set this value in case of encoder based system)
8.	Print direction	It displays in which direction we want to print i.e. left to right or right to left.
9.	# Of prints per object	Number of prints required on sensing of one object.
10.	Horizontal orientation	Its selection done as normal; and it depends on printing head mounting
11.	Vertical orientation	Its selection done as normal; and if head is operator side select it as mirrored.
12.	Horizontal resolution	300 dpi
13.	Vertical resolution	300 dpi



5.5.2. Press  key (lock) then screen will display as:






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5.5.3. Select the field to select the user type 'SERVICE' and then enter password respectively then press 'user change'.

5.5.4. For creating a new message press  key and then press 'New Message' option. Press 'Definitions' option and set the value as per following table:




5.5.5. Enter the desired TEXT in the Data entry column by selecting the field with the help of arrow keys displayed on HMI as  and enter the words and numeric value with the help of Key pad on HMI.

5.5.6. After entering all parameters press ACCEPT NEW VALUES.

5.5.7. For starting second line again follows the point no. 5.5.4 and set the HORIZONTAL and VERTICAL value to set the position of the line (NOTE: If not done then both lines will superimpose on each other).

5.5.8. After entering all parameters press ACCEPT NEW VALUES.

5.5.9. Press on Save as option to save the label.

5.5.10. Then press on Load option to run the file. For starting and stopping the print we have to press ,  and .

### 5.6. Procedure for creating the message label required to print with Domino Printer.

5.6.1. Required message details to be overprint on sticker label as per instruction given in the respective batch packing record. Following details can be overprint on sticker label:

- Mfg. Lic. No.
- Batch No./Lot
- Mfg. Date
- Exp. Date.
- GTIN Number (If applicable).
- Serial Number (If applicable).
- 2D code (If applicable).

5.6.2. Switch "ON" the power supply of the printer controller unit screen will display as;






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5.6.3. Press  key (lock) then screen will display as:

S.No.	Parameter name	Description
1.	Message height	12.7 For single printing Head
2.	Message width	50 (width can be changed as per requirement)
3.	Forward margin	20 (margin can be changed as per requirement)
4.	End margin	0 (margin can be changed as per requirement)
5.	Delay after input intell, micropurge	0 (value can be changed as per requirement)
6.	Print start mode	External i.e. ENCODER base or sensor base (External or Internal)
7.	Print speed mode	External i.e. ENCODER base or sensor base (External or Internal)
8.	Production speed	10 (Value can be changes as per requirement)
9.	Speed Modification	0 (Value can be changes as per requirement)
10.	Space between the elements of message	0 (Value can be changes as per requirement)
11.	Distance between print	0 (Value can be changes as per requirement)
12.	# of prints per object	1 (Number of prints required on sensing of one object).
13.	Print Direction	Normal (Depends upon the printing head mounting).
14.	Horizontal orientation	Normal; it depends on printing head mounting
15.	Vertical orientation	Normal; if head is operator side then select it as mirrored.
16.	Horizontal resolution	300 dpi (Value may be changed as per requirement)
17.	Vertical resolution	300 dpi (Value may be changed as per requirement)

5.6.4. Select the field to select the user type 'SERVICE' and then enter password respectively then press 'user change'.

5.6.5. For creating a new message press  key and then press 'New Message' option. Press 'Definitions' option and set the value as per table:

5.6.6. Enter the desired TEXT in the Data entry column by selecting the field with the help of arrow keys displayed on HMI as  and enter the words and numeric value with the help of Key pad on HMI.

5.6.7. After entering all parameters press 'ACCEPT NEW VALUES'



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5.6.8. For starting second line again follows the point no. 5.6.4 and set the 'HORIZONTAL' and 'VERTICAL' value to set the position of the line. (NOTE: If not done then both lines will superimpose on each other).

5.6.9. After entering all parameters press 'ACCEPT NEW VALUES' for saving the new changes done in label.

5.6.10. **Steps to create the identifier Batch field in label for Reetrak:**

Press the 'Create new' filed option and then press the 'Variable Text' Option and set the values as per following:

S.No.	Field name	Parameter
1.	Field Name	Batch No.
2.	Horizontal Position	0
3.	Vertical Position	0
4.	Font	Ocrb/ocr-b-10bt
5.	Font Size	7 (Font size may change as per requirement)
6.	Font Style	Complete
7.	Rotation	No Rotation
8.	Negative Printing	No
9.	Chimney Tower Print	No
10.	Visible Print	Yes
11.	Default Size	20
12.	Mandatory data for vtext	No

5.6.11. Press 'Accept new value' option for adding the field in label.

5.6.12. Press 'Move' option to move the field, press Left, Right, Up and Down to move the field in label area.

5.6.13. Press 'Escape' option to fix the field position in label area.

5.6.14. **Steps to create the identifier Expiry field in label for Reetrak:**

5.6.14.1. Press the 'Create new' filed option and then press the 'Variable Text' Option and set the values as per following:

S.No.	Field name	Parameter
1.	Field Name	EXP
2.	Horizontal Position	0
3.	Vertical Position	0
4.	Font	Ocrb/ocr-b-10bt



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5.	Font Size	7 (can be change as per requirement)
6.	Font Style	Complete
7.	Rotation	No Rotation
8.	Negative Printing	No
9.	Chimney Tower Print	No
10.	Visible Print	Yes
11.	Default Size	20
12.	Mandatory data for vtext	No

5.6.14.2. Press 'Accept new value' option for adding the field in label.

5.6.14.3. Press 'Move' option to move the field, press Left, Right, Up and Down to move the field in label area.

5.6.14.4. Press 'Escape' option to fix the filed position in label area.

### 5.6.15. Steps to create the identifier Expiry 2D field in label for Reetrak:

5.6.15.1. This field added if EXP field is needed to add in 2D Datamatrix barcode.

5.6.15.2. Press the 'Create new' filed option and then press the 'Variable Text' Option and set the values as per following:

S.No.	Field name	Parameter
1.	Field Name	EXP2D
2.	Horizontal Position	0
3.	Vertical Position	0
4.	Font	Ocrb/ocr-b-10bt
5.	Font Size	7 (can be change as per requirement)
6.	Font Style	Complete
7.	Rotation	No Rotation
8.	Negative Printing	No
9.	Chimney Tower Print	No
10.	Visible Print	No
11.	Default Size	20
12.	Mandatory data for vtext	No

5.6.15.3. Press 'Accept new value' option for adding the field in label.





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5.6.15.4. Press 'Move' option to move the field, press Left, Right, Up and Down to move the field in label area.

5.6.15.5. Press 'Escape' option to fix the field position in label area.

### 5.6.16. Steps to create the identifier GTIN field in label for Reetrak:

5.6.16.1. Press the 'Create new' field option and then press the 'Variable Text' Option and set the values as per following:

S.No.	Field name	Parameter
1.	Field Name	GTIN
2.	Horizontal Position	0
3.	Vertical Position	0
4.	Font	Ocrb/ocr-b-10bt
5.	Font Size	7 (Font size may change as per requirement)
6.	Font Style	Complete
7.	Rotation	No Rotation
8.	Negative Printing	No
9.	Chimney Tower Print	No
10.	Visible Print	Yes
11.	Default Size	20
12.	Mandatory data for vtext	No

5.6.16.2. Press 'Accept new value' option for adding the field in label.

5.6.16.3. Press 'Move' option to move the field, press Left, Right, Up and Down to move the field in label area.

5.6.16.4. Press 'Escape' option to fix the field position in label area.

### 5.6.17. Steps to create the identifier Serial No. field in label for Reetrak:

5.6.17.1. Press the 'Create new' field option and then press the 'Variable Text' Option and set the values as per following:

S.No.	Field name	Parameter
1.	Field Name	SERIAL
2.	Horizontal Position	0
3.	Vertical Position	0
4.	Font	Ocrb/ocr-b-10bt
5.	Font Size	7 (Font size may change as per requirement)



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6.	Font Style	Complete
7.	Rotation	No Rotation
8.	Negative Printing	No
9.	Chimney Tower Print	No
10.	Visible Print	Yes
11.	Default Size	20
12.	Mandatory data for vtext	No

5.6.17.2. Press 'Accept new value' option for adding the field in label.

5.6.17.3. Press 'Move' option to move the field, press Left, Right, Up and Down to move the field in label area.

5.6.17.4. Press 'Escape' option to fix the field position in label area.

5.6.18. **Steps to create the 2D Datamatrix Barcode field in label for Reetrak:**

5.6.18.1. Press the 'Create new' field option and then press the 'Barcode' Option and then press '2D Barcode option' set the values as per following:

S.No.	Field name	Parameter
1.	Field Name	BARCODE
2.	Barcode Type	Datamatrix GS1-128
3.	Data Entry	<< Data to be entered in Barcode >> eg: 01#GTIN#17#EXP2D#10#LOT#<GS>21SERIAL#
4.	Horizontal Position	0
5.	Vertical Position	0
6.	Coding Mode	Auto
7.	Symbol Size	26x26 (value may be changed as per requirement)
8.	Modify bar Height	2 (value may be changed as per requirement)
9.	Module Width	0.40 (value may be changed as per requirement)
10.	Font	Ocrb/ocr-b-10bt
11.	Rotation	No Rotation
12.	Negative Printing	No

5.6.18.2. Press 'Accept new value' option for adding the field in label.

5.6.18.3. Press 'Move' option to move the field, press Left, Right, Up and Down to move the field in label area.

5.6.18.4. Press 'Escape' option to fix the field position in label area.






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5.6.18.5. Press on 'Save as' option to save the label. Then press on Load option to run the file.

5.6.18.6. For starting and stopping the print we have to press ,  and .

5.6.18.7. A typical GTIN number would look like 8901463057985 which is of 13 digits where in:  
8901463 07 digits Stands for Company Prefix Number & in GTIN terms is also reflected as GS1. This doesn't change.

5 digits Stands for FG Code (Last 5 Digit from FG Code). This will change as per product

1 last digit Stands for Check Digit

Just for example, suppose if the FG code is FG005798, then the Base GTIN will be 890146305798 5

For the **Primary** level packaging the GTIN number will be start from no. 0, for example (08901463 05798 5)

For the **Secondary** level packaging the GTIN number will be start from no. 1, for example (1 8901463 05798 5)

For the **Tertiary** level packaging the GTIN number will be start from no. 5, for example (5 8901463 05798 5)

### 5.7. Precautions:

5.7.1. Do not take out Cartridge while machine is in ON conditions.

5.7.2. If machine displays cartridge ink level low change the cartridge if required.

5.7.3. For cleaning of cartridge always switch OFF the machine and use dry lint free cloth.

### 6.0 ABBREVIATION (S):

6.1. SOP : Standard Operating Procedure

6.2. HMI : Human Machine Interface

### 7.0 REFERENCES(S):

7.1. SOP: Status Labeling

7.2. SOP: Operation and setting of camera system installed at sticker labeling and leaflet outserter (Make – jekson).

### 8.0 ANNEXURE(S):

8.1. Nil

### 9.0 DISTRIBUTION:

9.1. **Master Copy** : Quality Assurance

9.2. **Controlled Copy (S)**: Production department (02), Quality Assurance (01)

9.3. **Reference Copy (S)** : Production department (02)



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### 10.0 REVISION HISTORY:

S.No.	CHANGE CONTROL No.	REVISION No.	REASON FOR REVISION	DETAILS OF REVISION	EFFECTIVE DATE
01	NA	NA	New SOP	NA	NA