



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Cleaning & Operation of Carton Overprinting machine with Pharmacode Reader (Make: Jekson)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

1.0 OBJECTIVE :

1.1 To lay down a procedure for cleaning and Operation of carton overprinting machine with pharmacode reader (Make: Jekson, Model: BPO-NXG).

2.0 SCOPE:

2.1 This procedure is applicable to the cleaning and operation of carton overprinting machine with Pharmacode reader (**Make:** Jekson, Model: BPO-NXG) in production area.

3.0 RESPONSIBILITY:

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

4.0 DEFINITION(S):

4.1 NA

5.0 PROCEDURE:

5.1 CLEANING:

- 5.1.1 Ensure that the carton-overprinting machine is switched "OFF".
5.1.2 Replace the "UNDER PROCESS" status label and affix "TO BE CLEANED" label on the machine.
5.1.3 Record the cleaning start time in equipment usage log as per SOP "Making entries in equipment usage and cleaning log sheet".
5.1.4 Remove the previous carton and label from conveyor belt.
5.1.5 Removed the previous stereotypes from the machine.
5.1.6 Clean the carton overprinting machine body and utility cables using a dry lint free cloth.
5.1.7 Clean the ink by lint free duster soaked with thinner.
5.1.8 Replace "TO BE CLEANED" status label with "CLEANED" status label with sign and date of production officer.
5.1.9 Clean the camera hard disc, monitor, CPU and connected wires with lint free duster.
5.1.10 Finally clean the area as per SOP "Cleaning of Production Area".
5.1.11 Record the cleaning end time in equipment usage log as per SOP "Making entries in equipment usage and cleaning log sheet".



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Issue Date:	Page No.:

5.2 PHARMACODE READER SETTING:

- 5.2.1 Switch “ON” the power supply from main electrical panel to UPS and then connect the machine to UPS by pressing “PUSH BUTTON” given on UPS.
- 5.2.2 System will start to initialize and it will take 180 seconds.
- 5.2.3 Different icons will appears on main screen, select “Jekson Code Reader” i.e. second number from left to right as displayed.
- 5.2.4 Now a window will appear on main screen that ask “Username” and “Password”.
- 5.2.5 Three level of “USER LOGIN” with their password as given below.

S.No.	Type of Functions	User Rights Assignment(Y/N)		
		Operator	Supervisor	Administrator (Production Head)
1.	Change the passwords and User Login ID	N	N	Y
2.	Select the old recipe for product and can change the batch number.	Y	Y	Y
3.	Prepare new recipe	N	Y	Y

- 5.2.6 For login, enter the username and password in specified field i.e. double click on text box to open the keyboard.
- 5.2.7 After enter the password select “Enter” option given on key.
- 5.2.8 Select “Accept” option to start the application and another options also given e.g. Exit” icon for to exit the application and “Turn Off” icon is allows the user to shut down the operation (as in Screen -2).
Note: If user is unable to login in a fixed number (3 nos.) of lockout attempts the user gets disabled, only user having administrator rights can enable the user to login.
- 5.2.9 After click on “Accept” icon the main screen will open as below.
- 5.2.10 For new product recipe select “GO” a new sub screen will open.
- 5.2.11 Select “In Loop” to obtaining image of the object.





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Review Date:

Issue Date:

Page No.:

- 5.2.12 Set the machine for carton by placing a carton between the machine guides under camera.
- 5.2.13 Switch “ON” the carton overprinting machine and pass one carton through it to grasp the image of pharmacode.
- 5.2.14 Pharmacode image make clear by adjusting the lens given in camera eye and make the image at center of screen by adjusting the position of camera and object sensor.
- 5.2.15 Set the red light of object sensor at edge of carton as it gives message to pharmacode reader to remain “ON” till object not pass under the pharma code reader
- 5.2.16 Select the “SCAN” from upper right side of main screen and pharmacode value will reflect in “PHARMACODE STATUS” situated at upper right side of screen.
- 5.2.17 If pharmcode value is not as per BPR then go to “TABLE VIEW” option given in main window.

Pharmacode (1)	
Value	27400
<input type="checkbox"/> CodeValue	0
PMSpeed	MEDIUM
SearchAccuracy	50
ExtendedSearchArea	<input checked="" type="checkbox"/>
Orientation	PICKET
Method	GrayScale
Direction	Right To Left
PharmaType	STANDARD
QuiteZone	6
ColorTolerance	9
Contrast	0
BarAngleDifference	20
CheckStandards	<input type="checkbox"/>
HeightPercent	30
Delete	Decode
Save	Close

- 5.2.18 Change the orientation of pharmacode from left to right or right to left by selecting the respective option.
- 5.2.19 Select the “DECODE AND SAVE” option given at lower side of “TABLE VIEW”.
- 5.2.20 Then select “TEST” option given at upper right side of main screen.
- 5.2.21 Select “RESCAN” from upper right side of main screen if previous image was not “OK” or with bad blocks and pharmacode value will reflect on the screen with green color outer ROI and inner ROI on screen.
- 5.2.22 Check that pharmacode value is as per given in BPR.
- 5.2.23 Again click on “In Loop” to deactivate it.
- 5.2.24 Then screen will show “SAVE AND RUN” option at lower right side corner as displayed.



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Issue Date:	Page No.:



5.2.25 If batch numbers is already saved on system than click on “Down ward arrow” and select the product and then enter batch number and click on “START INSPECTION”. The camera will be ready for inspection operation.

5.2.26 If new image is created on camera system than click on “Save and Run”.



5.2.27 System will ask “Model name”, double click on text box a new key will open and enter the product name. Again system will ask “Enter / Modify batch”, touch on text box and enter the batch number.

5.2.28 Click on “Start Inspection”, the camera will start the inspection operation.

5.2.29 If batch detail is already save then click on “Start Inspection”.

5.2.30 Run the machine after performing challenge test for carton.

5.3 CHALLENGE TEST:

5.3.1 After setting of Pharmacode reader, take a single carton of product, which has to be printed.

5.3.2 Pass that carton through machine, it should pass through the machine and get printed.

5.3.3 Now mark one or two extra lines in Pharmacode.

5.3.4 Again pass this carton with extra line through machine.

5.3.5 The machine gets stopped immediate and put the rejected carton into rejection box.

5.3.6 This challenge test shall be performed at start, after every two hours of operation, after any maintenance work and at end of operation.

5.3.7 Record the pharmacode challenge test observation in annexure-I (“Challenge Test for Pharmacode Reader”).

5.4 OPERATION:

5.4.1 Ensure the cleanliness of the machine.



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Page No.:

- 5.4.2 Take line clearance by production officer and QA officer.
- 5.4.3 Removed "CLEANED" status label with "UNDER PROCESS" status label after line clearance.
- 5.4.4 Issue the required rubber stereo of the batch/product for overprinting.
- 5.4.5 Fix the stereo on the block with the help of double-sided adhesive tape.
- 5.4.6 Put "ON" the power supply of the machine.
- 5.4.7 Place one carton on the line so that the carton will push to the printing area.
- 5.4.8 Apply ink on ink- roller to get good printing quality.
- 5.4.9 First take the impression on one carton to ensure the proper alignment of stereo.
- 5.4.10 After setting of the stereo take the first proof which should be clear and legible.
- 5.4.11 Get the first overprinted carton authorized by production officer and Q.A officer and affix the specimen to the BPR.
- 5.4.12 Enter the overprinting activity in the respective BPR.
- 5.4.13 After getting the approval start the overprinting activity.
- 5.4.14 Enter the operation time in equipment usage log sheet as per SOP ("Making entries in equipment usage and cleaning log sheet").

5.5 Shut Down Operation:

- 5.5.1 Select "Stop", than select on "Exit" the system will ask confirm exit.
- 5.5.2 Select "Yes", the system will come to main screen.
- 5.5.3 To shut down the system select "Turn Off", the system will ask confirm turn off.
- 5.5.4 Select "Yes", the system will shut down.

6.0 ABBREVIATION (S):

- 6.1 SOP : Standard Operating Procedure
- 6.2 TA / TTA : Technical Associate / Trainee Technical Associate
- 6.3 UPS : Un-interrupted Power Supply

7.0 REFERENCE (S):

- 7.1 SOP No. : Making entries in equipment usage and cleaning log sheet.
- 7.2 SOP No. : Cleaning of Production Area.



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Page No.:

8.0 ANNEXURE (S):

Annexure no.	Title of Annexure	Format no.	Mode of Execution
Annexure - I	Challenge Test for Pharmacode Reader		Log Book

9.0 DISTRIBUTION:

8.1 **Master Copy** : Quality Assurance

8.2 **Controlled copy (S)** : Production department (02), Quality Assurance (01)

8.3 **Reference copy (S)** : Production department (01)

10.0 REVISION HISTORY:

S.No.	VERSION No.	CHANGE CONTROLL NO.	REASON (S) FOR REVISION	DETAIL OF REVISION(S)	EFFECTIVE DATE



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Issue Date:	Page No.:

Annexure I

CHALLENGE TEST FOR PHARMACODE READER

FREQUENCY: AT START, AFTER EVERY TWO HOUR OF OPERATION, AFTER ANY MAINTENANCE WORK AND AT END OF OPERATION

No. of good cartons taken 04 No.

No. of bad carton taken 01 No.

DATE	TIME	# ACCEPTED	* REJECTED	RESULT OK / NOT OK	CHECKED BY	VERIFIED BY

Note down the no. of good carton in observation..

* Note down the no. of bad carton in observation.