



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: SOP for Procedure for Cleaning and Operation of DGFT system with Conveyor Belt and Camera Inspection System for Overprinting detail on Carton	Effective Date:
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1.0 OBJECTIVE:

To lay down a procedure for cleaning and operation of DGFT system with conveyor belt and camera inspection system for overprinting detail on carton.

2.0 SCOPE:

This procedure is applicable to cleaning and operation of DGFT system with conveyor belt and camera inspection system for overprinting detail on carton in production department.

3.0 RESPONSIBILITY:

Officer/Executive Production: Generation of DGFT bar code through ERP

Officer/Executive QA: Review and checking DGFT bar code through ERP

Production or shift In-charge: For any amendment in batch information.

Head Production and Head, Quality Assurance: Compliance to procedure.

4.0 DEFINITION (S):

Nil

5.0 PROCEDURE:

5.1 Cleaning

5.1.1 Ensure that the conveyor belt and computer is switched "OFF".

5.1.2 Remove "UNDER PROCESS" label and affix "TO BE CLEANED" label on the machine with signature of production and IPQA officer.

5.1.3 Remove all the previous packing material, rejected carton and its pieces present on the conveyor belt and dispose it as per SOP.

5.1.4 Clean the conveyor belt, rollers, carton guides, cables, camera lens and its body and computer of the machine with a clean dry lint free duster.

5.1.5 Clean the printing head by using tissue paper.



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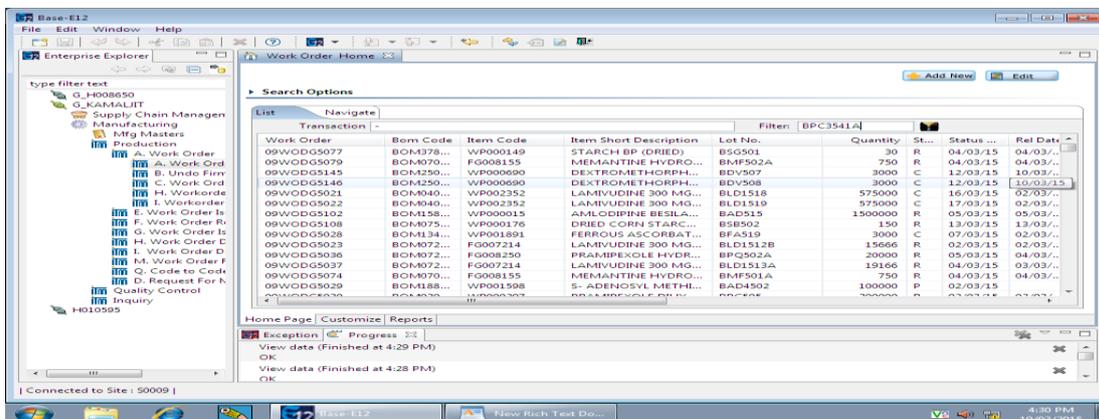
5.1.6 Replace the “TO BE CLEANED” status label with “CLEANED” status label with date and signature of the production officer.

5.2 Operation

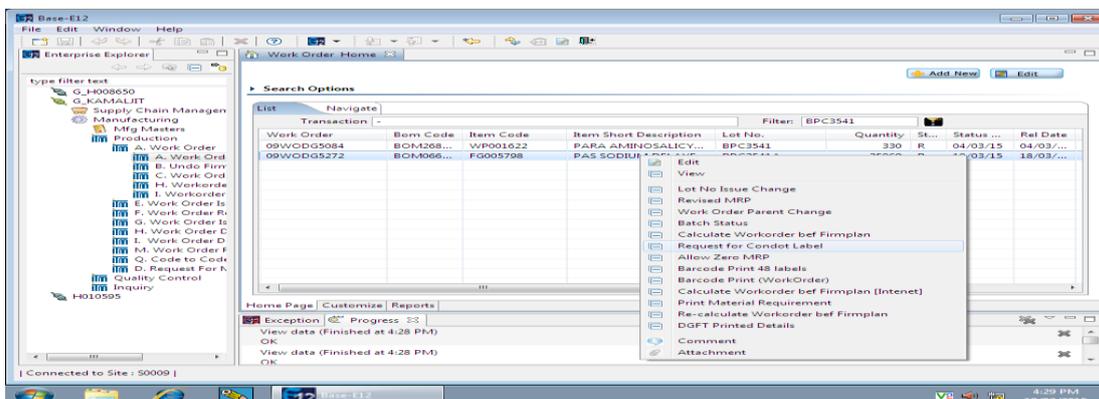
5.2.1 Switch “ON” the main from electric panel and start the UPS by pressing push button to start the conveyor belt.

5.2.2 Start the computer by pressing start push button of CPU.

5.2.3 Double click the “ERP icon” and put ERP login password, go to Manufacturing, production and then workorder , open w.order option refresh the w.order home screen select the particular B.no as shown in screen:



5.2.4 Right click the selected transaction and go to “Request for condot Label” as shown in screen:



5.2.5 Condot Label screen will be displayed, Select the secondary packing option for secondary packing and press the “GO” button as shown as below screen.



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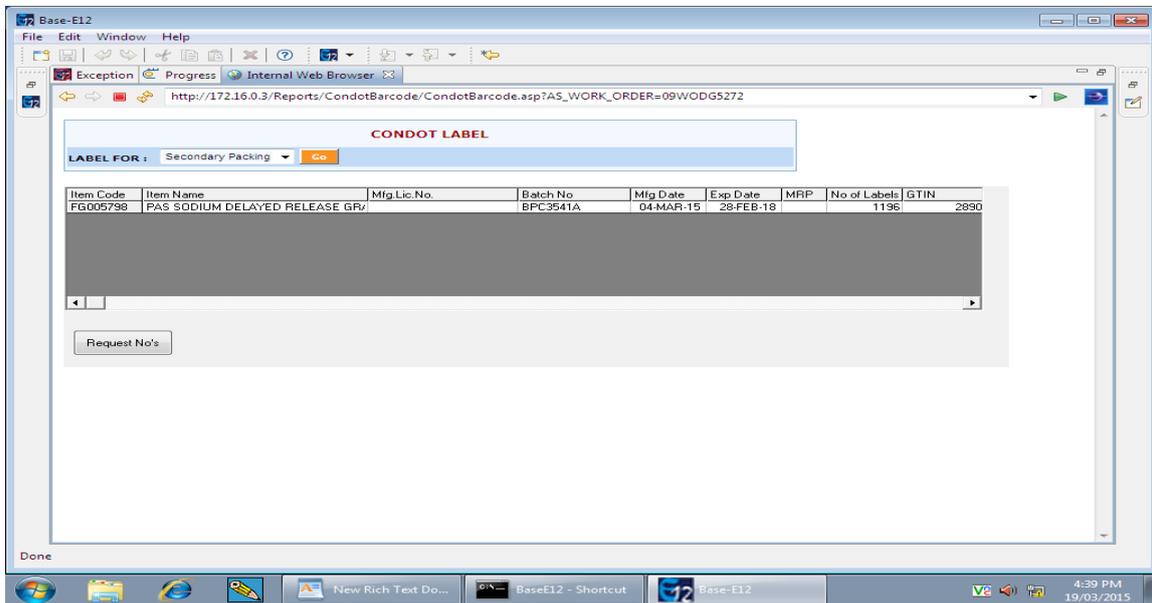
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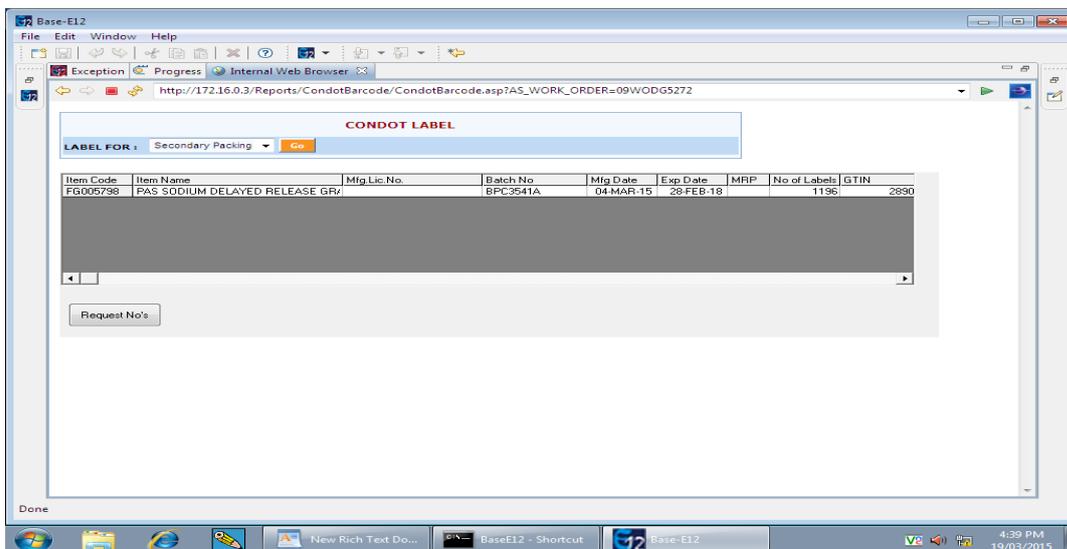
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5.2.6 The details of the product will appear ,check Batch No, Mfd. Date, Exp. Mfg.Lic.No., MRP, and No. of labels etc.as shown in screen.



5.2.7 Press the “Request NOS” and “Request Done Successfully” will appear on following screen.

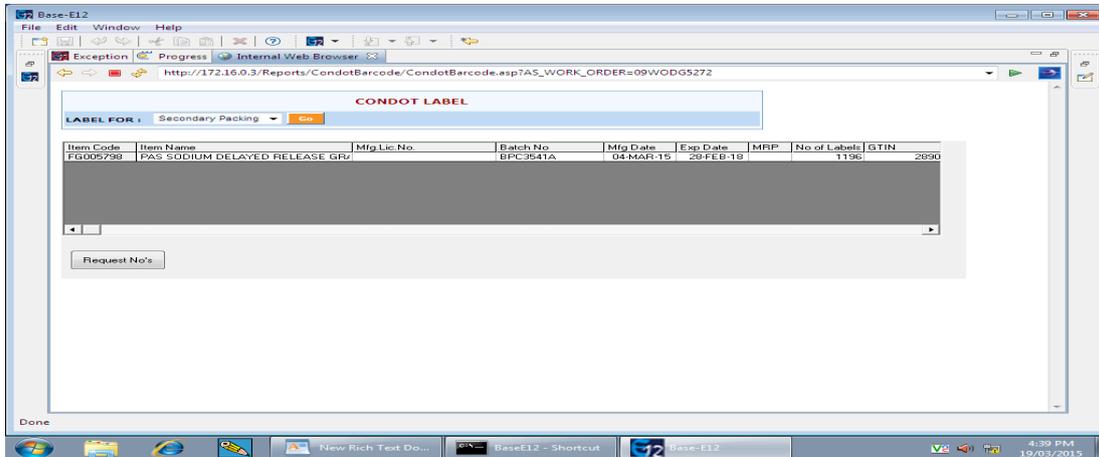


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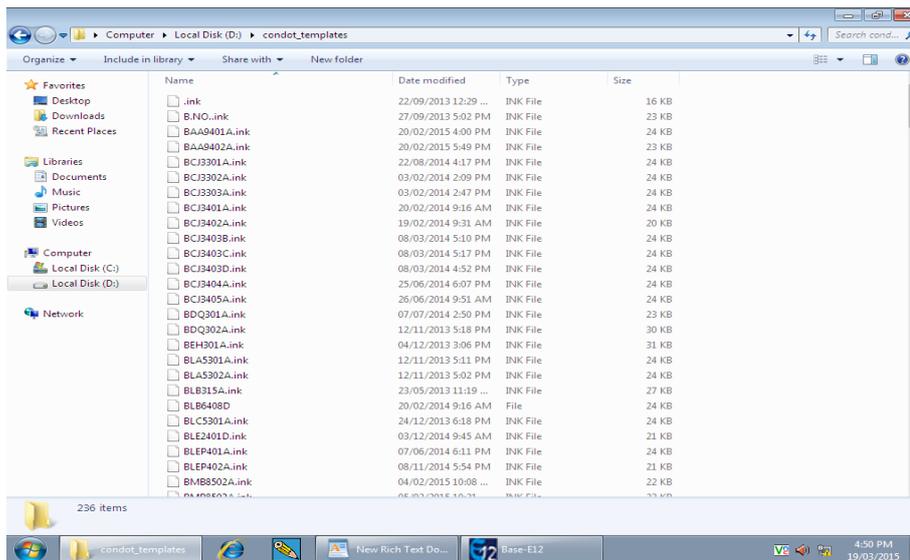
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5.2.8 Minimize the screen, Go to “D Drive” in My Computer and select “CONDOT TEMPLATE” as shown in screen :



5.2.9 Copy the existing file “eai301” paste it and rename the file with batch no. as shown in screen:

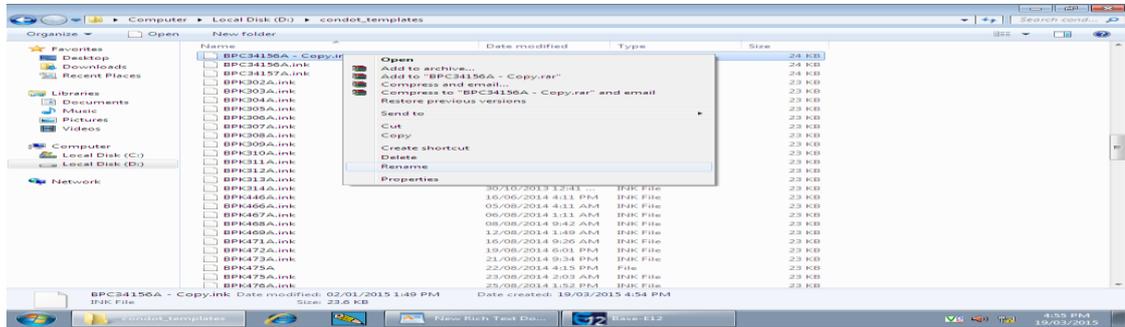


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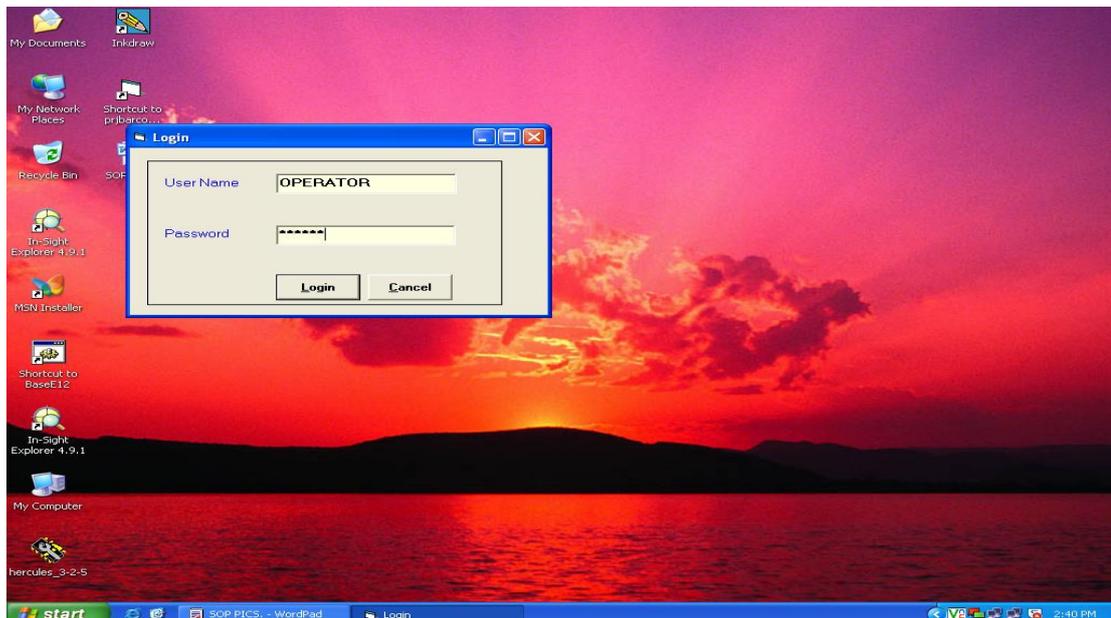
5.2.10 To open 'inkdraw':

5.2.10.1 Following table is given according to user rights assignment to open 'inkdraw':

S.No.	Type of Functions	Type of user	
		Rights to operator	Rights to shift/ production incharge
1.	Amendment if any	No	Yes
2.	Recipe preparation	No	yes
3.	Open the 'inkdraw' window.	Yes	Yes

5.2.10.2 Challenge test for valid/ invalid user ID and password done as per attached Annexure-III.
Frequency : After every three month.

5.2.10.2 Make double click on 'inkdraw' icon from desktop window shall be ask for 'user name and password' as given below:





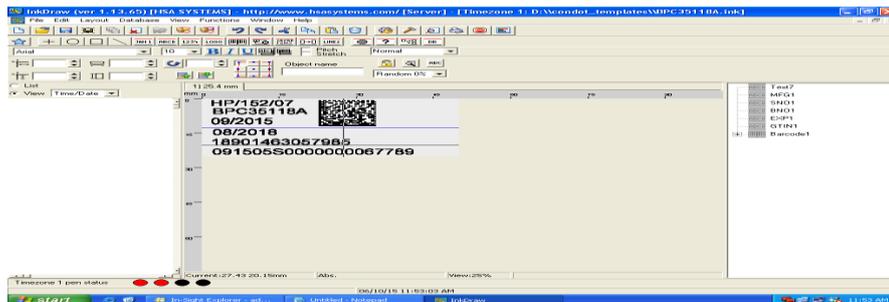
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5.2.10.3 Enter 'user name' and 'password' in the above given screen and following screen will be displayed:

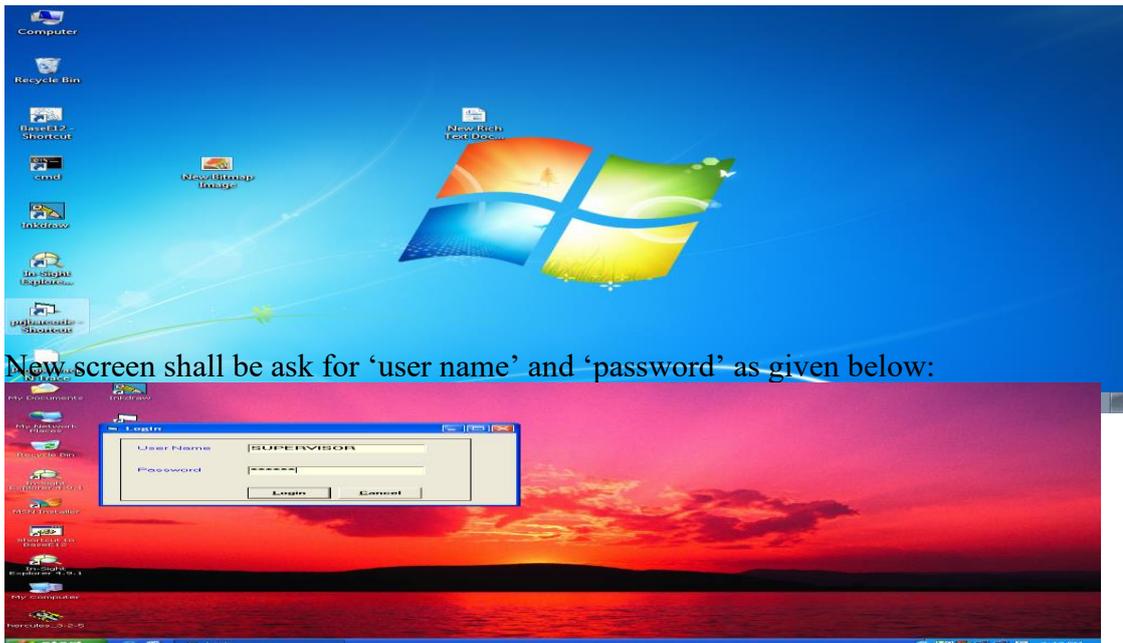


5.2.10.4 Enter the batch information in the 'condot template' and then save.

5.2.10.5 Now minimize the 'inkdraw' screen.

5.2.11 **To open 'Shortcut To prjbarcode shortcut':**

5.2.11.1 Go to desktop, select "Shortcut To prjbarcode shortcut" from the below given screen :



5.2.11.2 New screen shall be ask for 'user name' and 'password' as given below:

5.2.12 Following table is given with users and their rights assignment.



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S.no.	Type of Function	Type of user	
		Rights of Supervisor	Rights of Shift In-charge or production In-charge
1.	Amendment if any	No	Yes
2.	Previous product deletion	No	Yes
3.	To Open the "Shortcut to prjbarcode shortcut" & access the 'trial or print' option.	Yes	Yes

5.2.13. Challenge test for valid/ invalid user ID and password done as per attached Annexure-III.

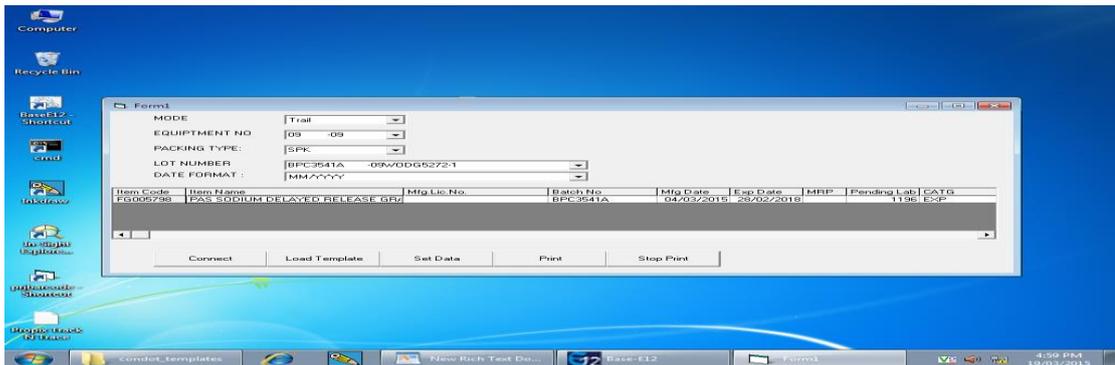
Frequency : After every three month.

5.2.14 Enter 'user name' and password than select 'login' from above window and 'Form 1' Screen will open with three mode operation e.g. Trial made ,Print mode and Amendment mode:

5.2.14.1 **Trial mode :**

5.2.14.1.1 Only print setting and print appearance can be check in this mode.

5.2.14.1.2 Select the 'trial' option from pop up help against the 'mode' option given in window as:



5.2.14.1.3 Select 09 -09 option with pop up help against the given 'EQUIPMENT NO.' in given above window.

5.2.14.1.4 Select 'SPK' option with pop up help against the given 'PACKING TYPE' in above given window.

5.2.14.1.5 Select required batch no. from the option with pop up help against the given 'LOT NUMBER' in given above window.

5.2.14.1.6 After selection of lot no. the details will be displayed such as item code,item name as shown in screen.



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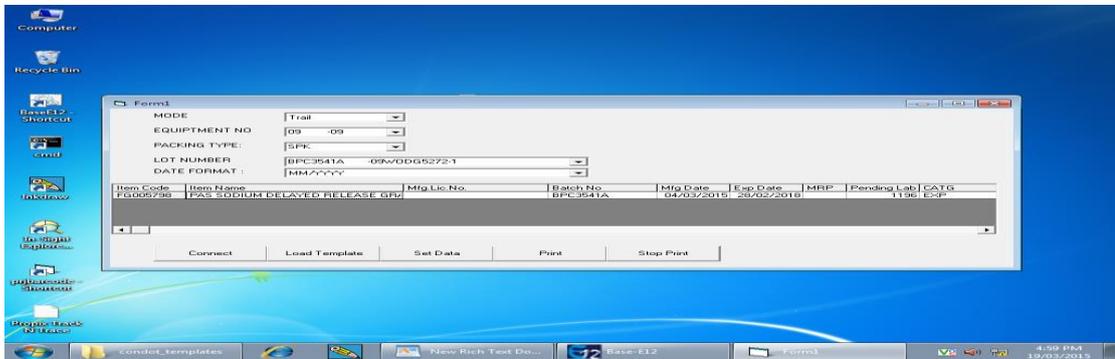
Effective Date:

Supersedes: Nil

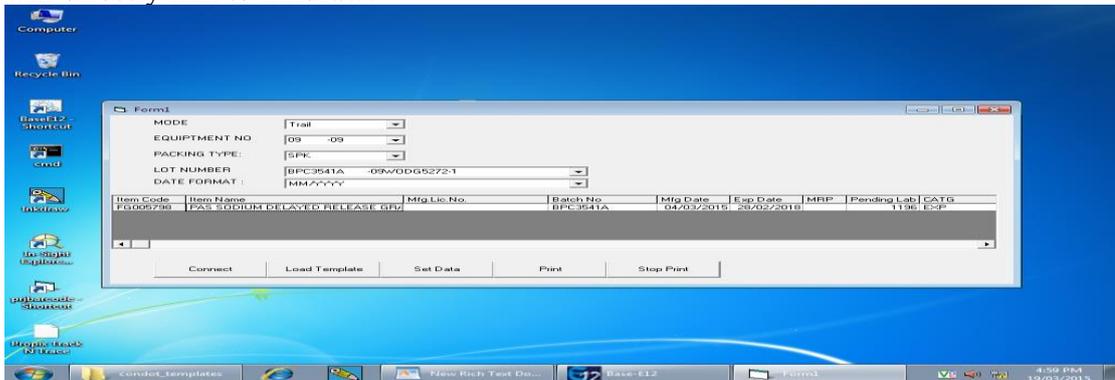
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5.2.14.1.7 After selection of date format automatically batch information appear in the screen and than check all batch information for correction and than click to connect option as shown in screen. Before click on to connect option please ensure that Inkdraw (OBJ) file is open. This will directly link to Inkdraw.



5.2.14.1.8 Then select "LOAD TEMPLATE" a dummy screen will be displayed and then select "SET DATA" the following screen will be displayed as shown :





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Note: 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.

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

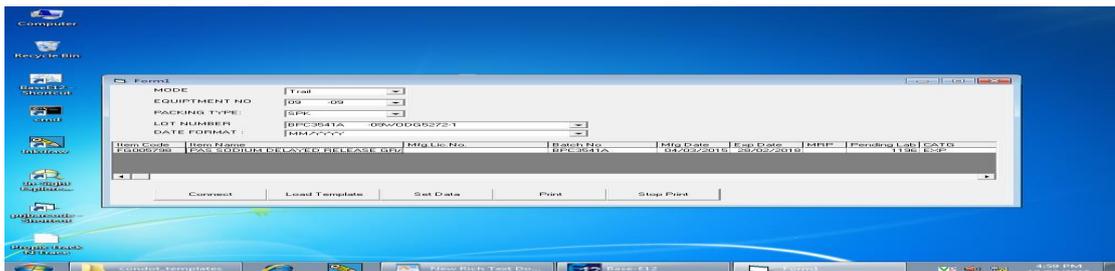
X 1 last digit Stands for Check Digit (Auto Generated by System)

Just for example, suppose if the FG code is FG005798, then the Base GTIN will be 8901463 05798 5

For the **Primary** level packaging the GTIN number will be start from no. 0, for example (0 8901463 05798 5)

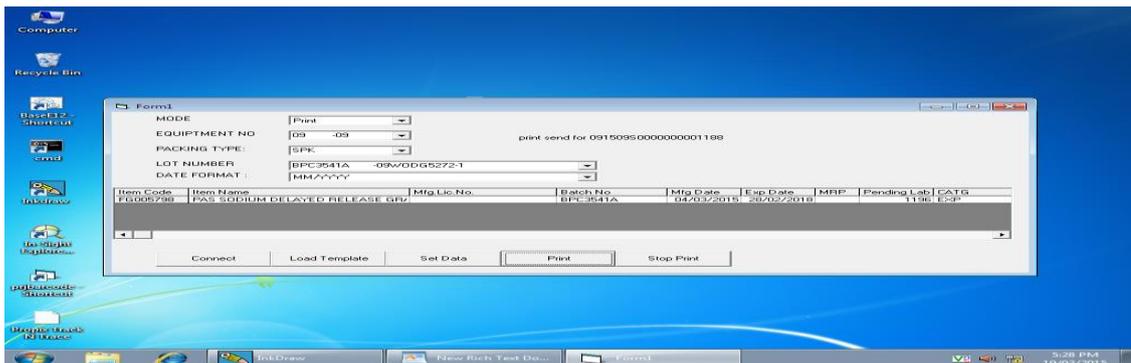
For the **Secondary** level packaging the GTIN number will be start from no. 1, for example (1 8901463 05798 5)

5.2.14.1.9 After checking the details displayed on screen go to “PRINT” option given at lower side of below screen. If in any reason the printing to be stopped than select “STOP” Print option, the printing will be stopped (when again print command is given the serial no. from where it is stopped will continue for bar code).



5.2.14.2 Print mode:

5.2.14.2.1 Select the 'print' option with pop up helps against the 'mode' option given in window as:





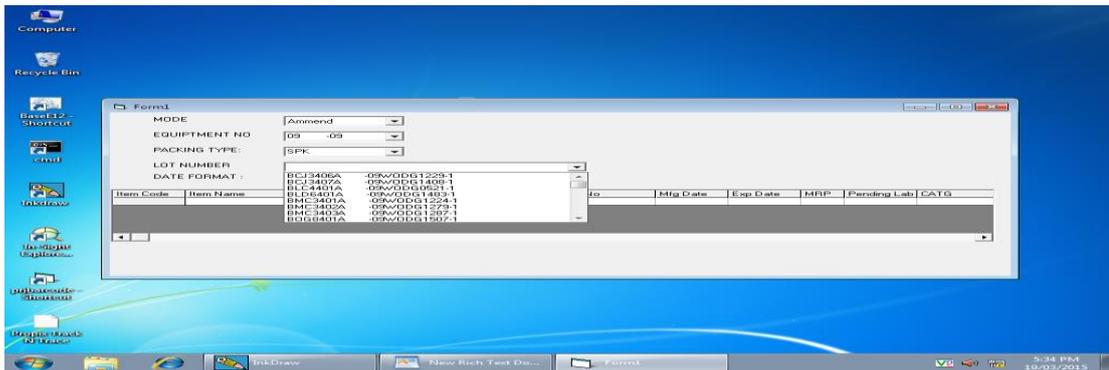
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- 5.2.14.2.2 Take the print and check the visibility of the print.(Take the approval on carton by the concerned production officer and Q.A. officer).
- 5.2.14.2.3 Scan and verify the DGFT barcode by using manual barcode scanner connected to PC, open the note pad, place the red light beam of scanner at the bar code to be scanned.
- 5.2.14.2.4 Bar code no. will display on note pad, take printout of bar code scanned.
- 5.2.14.2.5 If print is not in required area then click on “PARAMETER” icon and set it by changing sensor start value / Velocity (If Required).
- 5.2.14.3 **Amendment mode:**
- 5.2.14.3.1 If any amendment to be made in batch information after print request command done, the only shift in-charge or production in-charge is authorized for amendment through ‘user name’ and password’ protection facility as per given in point no. 5.2.13.
- 5.2.14.3.2 Take approval from IPQA for any amendment to be done by filling detail in the attached Annexure-II.
- 5.2.14.3.2 Go to desktop, select “Shortcut To prjbarcode shortcut” from the desktop screen and window shall ask for ‘user name’ and password’.
- 5.2.14.3.3 Enter ‘user name’ and password and ‘Form 1’ Screen will open.
- 5.2.14.3.4 Then select ‘amendment’ option from pop up helps as shown in screen.



- 5.2.14.3.5 After selection of the above options following screen will display with update option, make required
- 5.2.14.3.6 Than select the “Print option” in mode section as shown as below screen:



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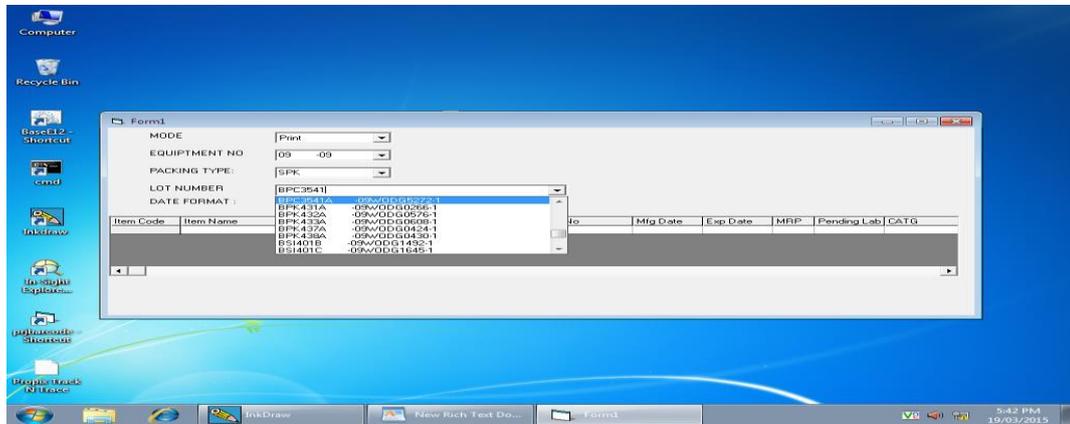
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5.2.14.3.7 After the amendment done by production, IPQA shall close the it by verifying and sign the amendment done in DGFT system as per Annexure-II.

5.2.15 **Closing request of previous product / batch no. in system:**

5.2.29 When previous product/batch completed than it need to delete from system and for this follow the point no. from 5.2.14.3.1 to 5.2.14.3.6.

5.2.30 Than select the 'close request' option from the window and previous product / batch no shall be deleted from system.

5.2.31 Close the window by selecting cross option at right side of window.

5.3 **CAMERA INSEPECTION SYSTEM FOR OVERPRINTING DETAIL ON CARTON:**

5.3.1 Select the icon "INSIGHT EXPLORER SHORTCUT" from the window.





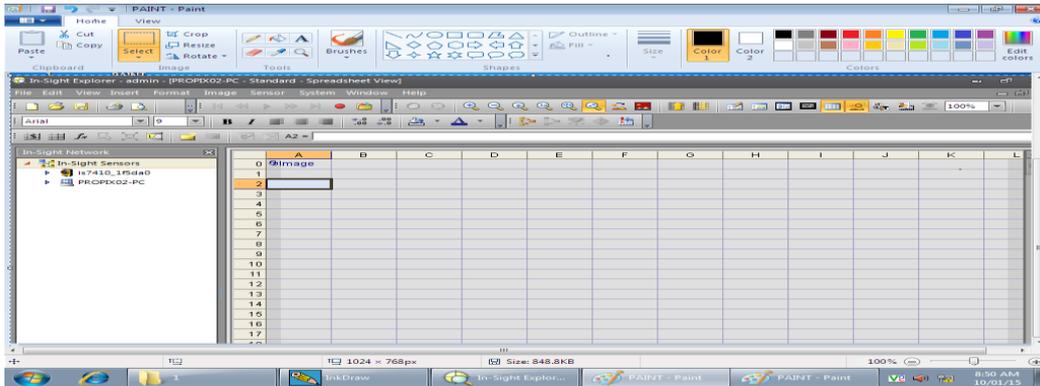
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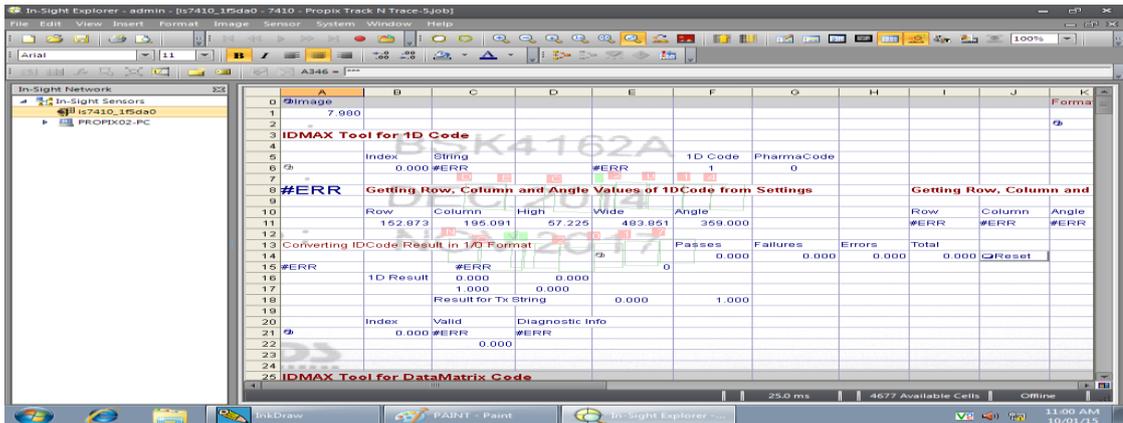
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5.3.2 New window will be displayed as given below and select ‘is 7410_1fsda0’.



5.3.3 New window will be displayed as shown :



- 5.3.4 Select the add or remove button from the upper right side of screen to make power “OFFLINE” or “ONLINE” and a message will come that “ARE YOU SURE YOU WANT TO GO OFFLINE”.
- 5.3.5 Select the “YES” from option.
- 5.3.6 Select the icon “CUSTOM VIEW” from the upper right side of the screen and camera will be ready to capture the image.
- 5.3.7 Now set the camera that it could make clear and complete picture of overprinting detail by sliding it upper or lower and left or right side.
- 5.3.8 Pass the approved carton through the camera and get the image of overprinting detail on carton.
- 5.3.9 Press the icon “CUSTOM VIEW” and a new window will be displayed as given below.

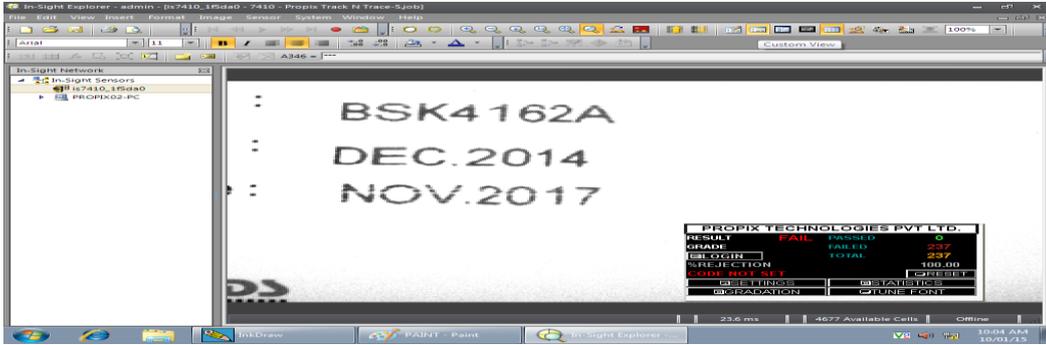


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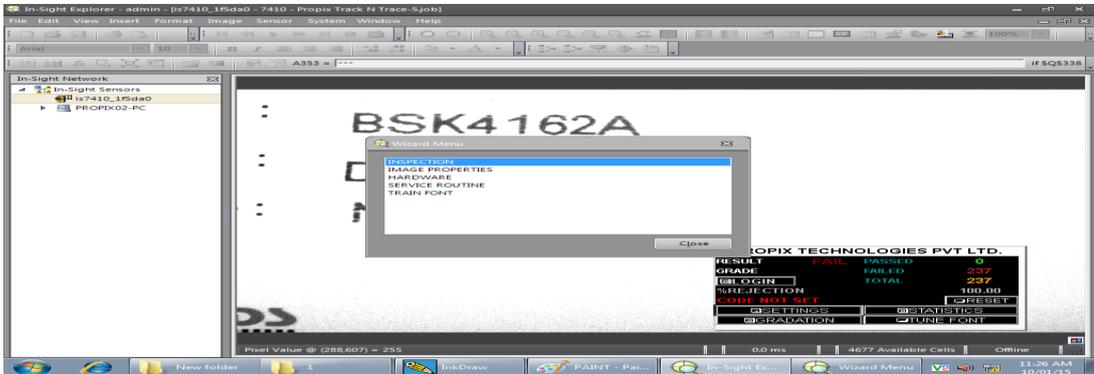
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5.3.10 Select the “SETTING” from the window a menu will be displayed as given.



5.3.11 Select the “INSPECTION” by double click from the above window and new window will be displayed as given below.



5.4 SETTING OF CARTON OVERPRINTING WITHOUT 2D BARCODE :



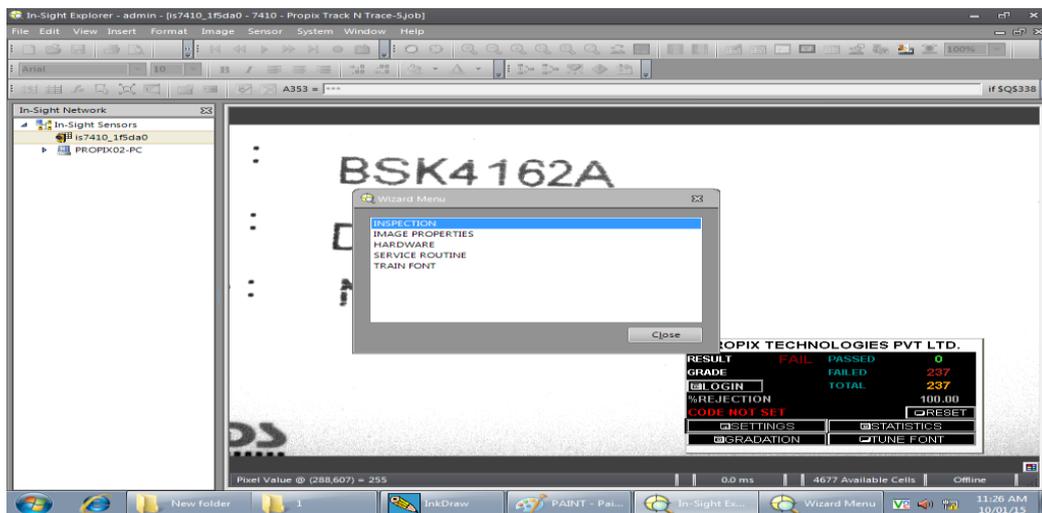
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- 5.4.1 Select the “EXTRA LINE” e.g. LINE 6,LINE 7,LINE 8,LINE 9, LINE 10 and enter the required message into space given linewise.
- 5.4.2 Press the “OK”
- 5.5 **CARTON OVERPRINTING WITH 2D BARCODE :**
- 5.5.1 Select the GTIN,LOT NO.,EXPIRY,MFGD. Etc. and enter the message into lines as required for batch overprinting.
- 5.5.2 Press the “OK”
- 5.6 **PHARMACODE SETTING IN CAMERA:**
- 5.6.1 Select the “1D CODE” and then select “SET ROI”.
- 5.6.2 Select the region of interest and affix it on pharmacode on screen.
- 5.6.3 Now select the “PHARMACODE” from pop up window.
- 5.6.4 Select the “1D VARIFY” as given in above window and put the pharmacode value into space given for verification.
- 5.6.5 Select the “MENU” option and previous window will be displayed then select the “TRAIN FONT” from the window.





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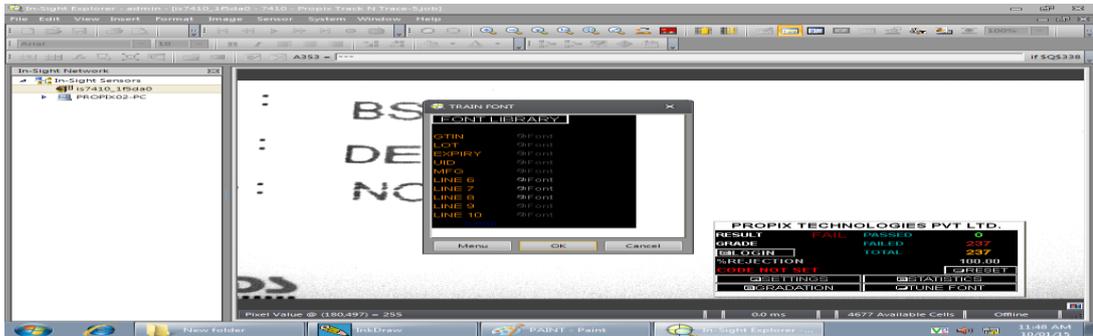
Supersedes: Nil

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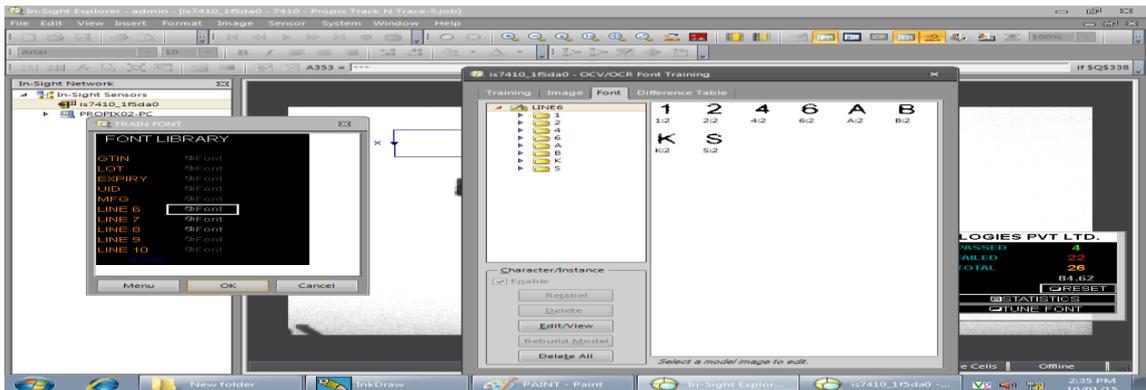
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5.6.6 Window will displayed as given below and double click on the line which need to teach.



5.6.7 New window will be displayed as shown and select the 'FONT' then select 'DELETE'.





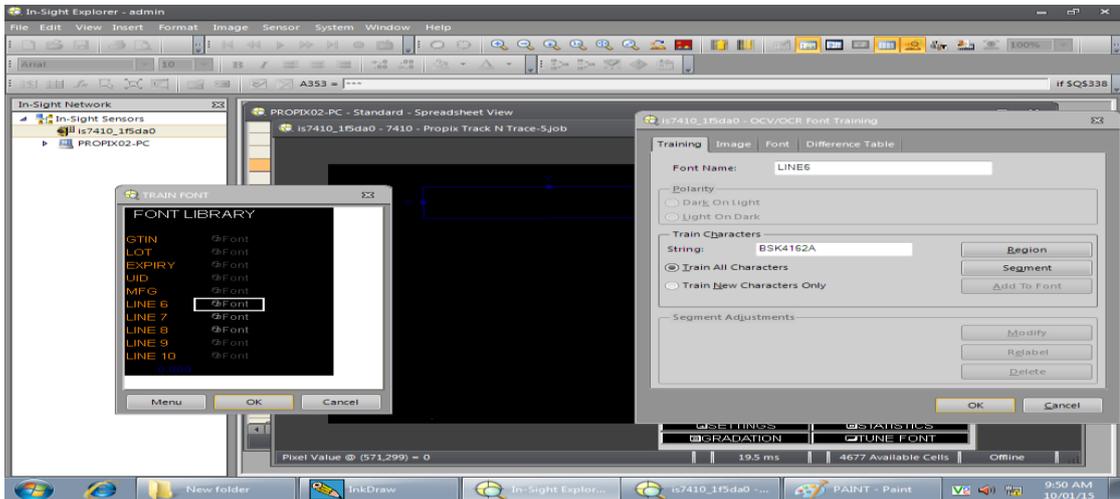
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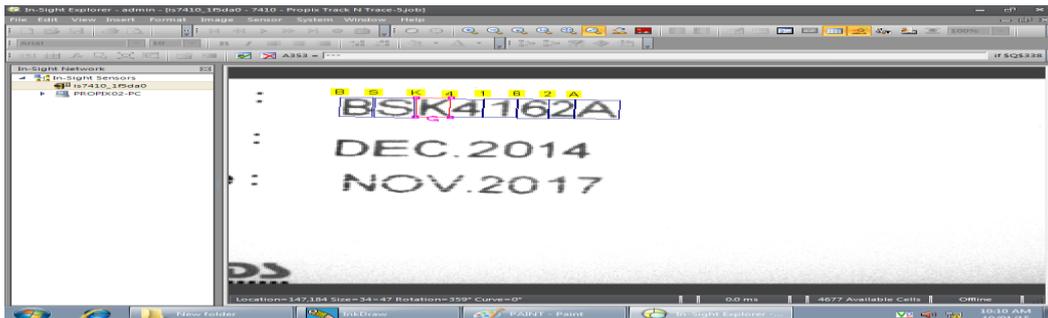
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5.6.8 Now select the “TRAINING” from the window and select the “REGION”



5.6.9 Select “SEGMENT” from the window. It will split the message into word level segments. This shows kind of overlapping if any between the message as displayed.



- 5.6.10 Select the “MODIFY” and remove the overlapping in message by giving the sufficient region to each digit.
- 5.6.11 Follow the similar procedure from points 5.3.1.15 to 5.3.1.20 to set all messages.
- 5.6.12 Give region to each word or digit and remove overlapping if any.
- 5.6.13 Select the “ADD TO FONT” and then go for “SAVE”.
- 5.6.14 Double click on the message and select “OK”.



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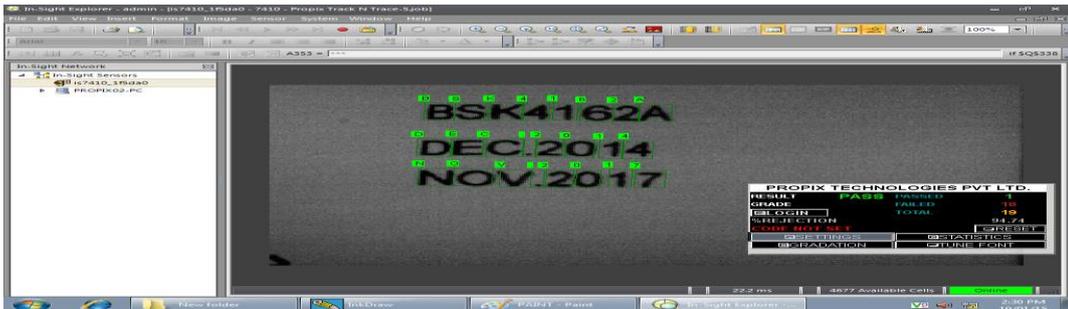
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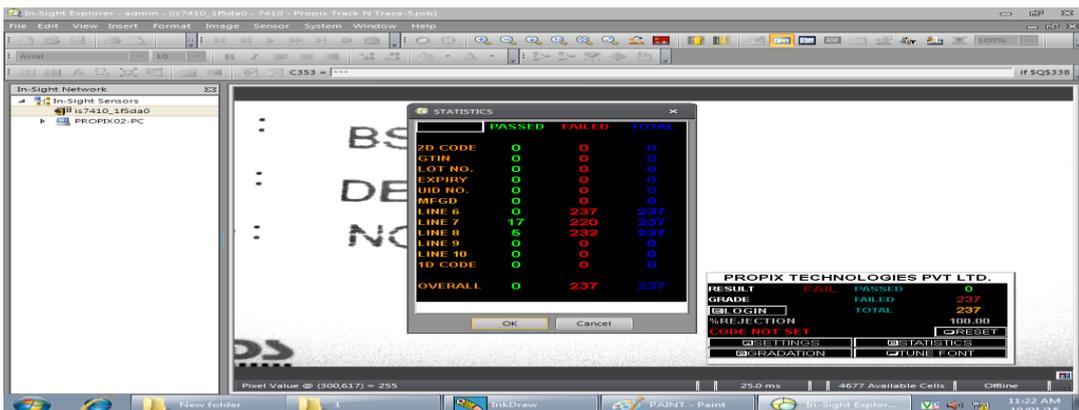
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5.6.15 Green colour region surrounding each segment shows no overlapping in the message as displayed in window.



5.6.16 Select the "CUSTOM VIEW" from the upper right side on the screen and select "STATISTICS" option from the window. It shows all kind of rejection with overall quantity of overprinting rejection.



5.7 **SETTING OF EJECTOR SYSTEM :**



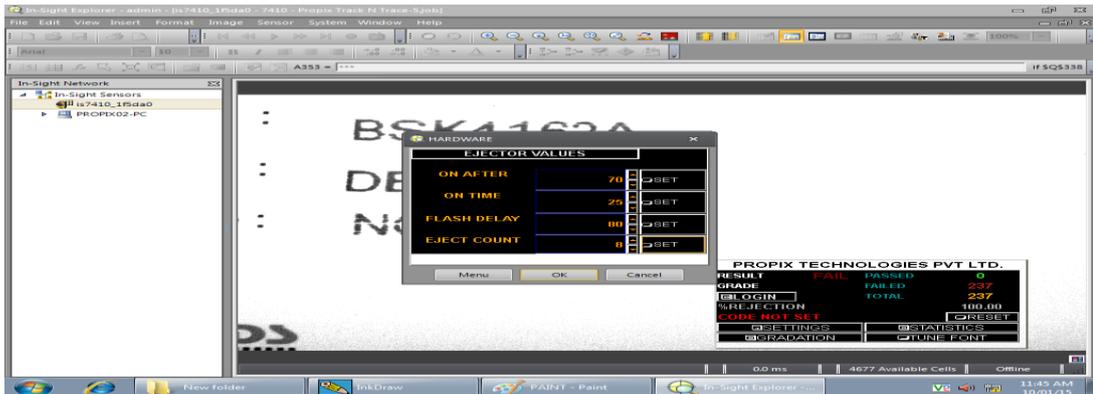
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- 5.7.1 Select the “CUSTOM VIEW” from upper right side of the screen and then select “SETTING” and then go to “HARDWARE” following window will be displayed.



- 5.7.2 Ejection mechanism can be control by entering some specific parameters value as shown above.
- 5.7.3 Ensure that difference between the object sensor and target sensor(Near ejector system) shall be not less then 300 mm and not more then 500 mm.
- 5.8 **CAMERA CHALLENGE TEST:**
- 5.8.1 **CHALLENGE TEST FOR GOOD CARTON:**
- 5.8.1.1 After approval of overprinting detail pass the overprinted good carton through the machine.
- 5.8.1.2 It must be pass.
- 5.8.1.3 Record the camera challenge test in Annexure-I
- 5.8.2 **CHALLENGE TEST FOR 2D CODE :**
- 5.8.2.1 Mark extra lines or deface the 2D CODE by making big dot in center of 2D code with marker.
- 5.8.2.2 Now pass the carton through camera.
- 5.8.2.3 It must be rejected.
- 5.8.2.4 Record the camera challenge test in Annexure-I
- 5.8.3 **CHALLENGE TEST FOR CARTON WITHOUT 2D CODE(Applicable For Overprinting Detail Only) :**
- 5.8.3.1 Deface the overprinting detail with marker by overlapping the last digit of B.no. and pass it through camera.
- 5.8.3.2 It must be rejected.
- 5.8.3.3 Record the camera challenge test in Annexure-I
- 5.8.4 **CHALLENGE TEST FOR CARTON WITH PHARMA CODE :**
- 5.8.4.1 Mark extra line by marker in the pharmacode.



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5.8.4.2 Now pass the carton through camera.

5.8.4.3 It must be rejected.

5.8.4.4 Record the camera challenge test in Annexure-I.

5.8.5 CHALLENGE TEST FOR DOUBLE CARTON:

5.8.5.1 Pass the double carton together through the DGFT system with camera inspection system.

5.8.5.2 Both carton must be rejected by rejection system and must be fall into collection box.

5.8.5.3 Record the observation in Annexure-I.

6.0 **ABBREVIATION (S):**

DGFT: Directorate General of Foreign Trade.

7.0 **REFERENCE (S):**

SOP No.: Disposal of excess printed material.

8.0 **ANNEXURE (S):**

Annexure-I: Challenge test for camera inspection system of DGFT bar code for overprinting detail on carton.

Annexure-II: Log for amendment if any in product detail in DGFT system during packing.

Annexure-III: Challenge test for accessing the user ID & password protection system.

9.0 **DISTRIBUTION:**

9.1 **Master Copy:** Quality Assurance

9.2 **Controlled Copy (s):** Production, Quality Assurance

9.3 **Reference Copy (s):** Production



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: SOP for Procedure for Cleaning and Operation of DGFT system with Conveyor Belt and Camera Inspection System for Overprinting detail on Carton	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

ANNEXURE I

Procedure for cleaning and operation of DGFT system with conveyor belt and camera inspection system for overprinting detail on carton

FREQUENCY: At start, after every two hours and at end of operation.

No. of good cartons taken 02 Nos.

No. of bad carton taken 01 No.

DATE	TIME	CHALLENGE TEST FOR					RESULT OK/NOT OK	CHECKED BY (Production)	VARIFIED BY(IPQA)
		* GOOD CARTON	# CARTON WITH 2D CODE	# CARTON WITH OVERPRINTING DETAIL(where 2D BAR CODE not applicable)	# CARTON WITH PHARMACODE	¥ DOUBLE CARTON			

* Mark "OK" in observation if pass and mark "NOT OK" if rejected.

Mark "OK" in observation if rejected and mark "NOT OK" if pass & ¥ Mark "OK" in observation if both cartons rejected and mark "NOT OK" if one or both carton passed.



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ANNEXURE III

CHALLENGE TEST FOR DIFFERENT USER ID & PASSWORD PROTECTION SYSTEM PROVIDED IN DGFT BAR CODE SYSTEM WITH CONVEYOR BELT AND CAMERA INSPECTION SYSTEM FOR OVERPRINTING DETAIL ON CARTON (JEKSON VISION)

EQUIPMENT NAME												
EQUIPMENT ID												
Frequency: After every three months										RESULT OK/NOT OK	CHECKED BY (Production)	VERIFIED BY (IPQA)
* CHALLENGE TEST FOR INKDRAW' OPTION					# CHALLENGE TEST FOR "Shortcut to prjbarcode shortcut" option							
• TO OPEN BY VALID USER ID & PASSWORD			# TO OPEN BY INVALID USER ID & PASSWORD		* TO OPEN BY VALID USER ID & PASSWORD		# TO OPEN BY INVALID USER ID & PASSWORD					
DATE / TIME	*FOR OPERATOR	*FOR SHIFT/PRODU- CTION INCHARGE	#FOR OPERATOR	#FOR SHIFT/PROD- UCTION INCHARGE	*FOR SUPERVISOR	* FOR SHIFT / PRODUCTION INCHARGE	#FOR SUPERVISOR	# FOR SHIFT / PRODUCTION INCHARGE				

*Mark OK in observation if access of user ID & password occurs otherwise mark Not OK # Mark ok in observation if access of user ID & password is denied otherwise mark NOT OK.