



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Cartonator Machine (Model: WKH-100)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Vernacular SOP: No

1.0 OBJECTIVE:

1.1 To lay down a procedure for Cleaning and Operation of Cartonator machine (Model: WKH – 100).

2.0 SCOPE:

2.1 This procedure is applicable to Cleaning and Operation of Cartonator machine in Production department.

3.0 RESPONSIBILITY:

3.1 Technical Associate: For cleaning and Operation.

3.2 Officer/ Executive Production: For Verification

3.3 Head Production: SOP Compliance.

3.4 IPQA: Line clearance and online process confirmation.

4.0 DEFINITION (S):

4.1 Done By- The activity performed by the Person

4.2 Verified By- Evidence that establish or confirm the accuracy or truth of activity

5.0 PROCEDURE:

5.1 CLEANING:

5.1.1 Remove 'EQUIPMENT STATUS' label and affix 'UNDER CLEANING' label on the machine with date and sign of production officer.

5.1.2 Record the cleaning start time in equipment usage log as per SOP "Making entries in equipment usage and cleaning log sheet".

5.1.3 Switch 'OFF' the utility supply before cleaning.

5.1.4 Remove Secondary packing material i.e. Carton, Leaflet, booklet and Embossing dies/stereo of previous product (Whichever is applicable) from the cartonator machine.

5.1.5 Clean the Link conveyor belt, carton magazine, Leaflet feeding assembly, Booklet feeding assembly and other parts of machine with the help of clean lint free duster & MMI and utility cables should be clean with Dry lint free duster.

5.1.6 In case of Changeover of product with different actives / colour / descending potency.

5.1.7 Mop metal part of the machine by using clean lint free duster soaked with filtered 70% v/v IPA solution followed by dry lint free duster and acrylic guard with the help of dry lint free cloth. Ensure no any traces of the lubricating oil/ grease/ any other foreign substance left behind on the cam (surface at which carton and blister travels).



STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Cleaning and Operation of Cartonator Machine (Model: WKH-100)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

5.1.8 Replace the 'UNDER CLEANING' status label by 'CLEANED' status label.

5.1.9 Frequency: Daily After completion of operation.

5.2 MACHINE SETTING:

5.2.1 Switch on the mains and press CONTROL ON switch to start MMI.

5.2.2 Open the valve of compressed air.

5.2.3 MENU SCREEN: This screen is the main routing point for access to various sets of screens:

- Operator Controls
- Set Parameters
- Servo Parameters
- Length or Factory Setting
- Recipe Function
- Manual Function
- Production Data
- Diagnostics
- Three other option are LOGIN, ALARMS, LOGOUT.

5.2.4 **Set Parameter (Two separate screen appear as per respective machine): As per requirement adjust Process Parameters of below points**

1. Number of Blisters per carton
2. Blister divert air blow delay
3. Blister divert cycle delay
4. Blister drop end limit
5. Carton pick air blow duration

NOTE: Other keys are: Carton BCR, Leaflet BCR, Booklet BCR, Menu, Barcode Reader, Angle and Rejection, Next.

5.2.4.1 Number of blister per carton is changed according to pack size of the batch.

5.2.4.2 Blister divert air blow delay, Blister divert cycle delay, Blister drop end limit and Carton pick air blow duration are changed whenever applicable i.e. depending upon the speed of the product.

5.2.5 Screen Next Display SET PARAMETER - 2 screen as -

Carton Rotary Act. Counter This is number of Machine cycles after which Carton Rotary Actuator is turned On. This parameter is valid only for an Extended Carton Magazine.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Cleaning and Operation of Cartonator Machine (Model: WKH-100)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

Blister Conveyor Off Delay - This is Blister Conveyor Off Delay. **Multi-Stage Blister Drop (Yes / No)** - Enable or disable Multi-stage blister drop

5.2.6 Set Angle Parameters:

1. Sensor Check Angle (Two different screen for separate machine as) -

- Product level low check
- Product level high check
- Carton Pick sensor check
- Leaflet/Booklet check on dropper
- Leaflet/Booklet Jam check On GUK
- Leaflet/Booklet push check

And second screen as -

Product Level Low Check - The Correct quantity of Blisters is checked on the Blister Conveyor in the angle band defined from START to END.

Product Level High Check - The Correct quantity of Blisters is checked on the Blister Conveyor in the angle band defined from START to END

Carton Pick Sensor Check - The Carton drop check is done in the angle band defined from START to END.

Carton Rejection Failure - The Carton Rejection Failure Start and End angles are set to confirm if the reject carton is rejected by the rejection cylinder.

Next option gives second screen of Sensor check angle 2 as

LEAFLET CHECKON DROPPER - The Leaflet drop check is done in the angle band define from START to END.

BOOKLET CHECK AT INSERTION - The booklet presence will be checked in the defined degrees.

LEAFLET JAM CHECK ON GUK - This is the angle at which the leaflet Jam Check on GUK.

LEAFLET PUSH CHECK - This is the angle at which the leaflet push check is done.

Pneumatic solenoid angles screen (There are two different screen as per respective machine): one is as



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Cartonator Machine (Model: WKH-100)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- Carton Pick
- Carton Reject
- Carton Rotary Actuator
- Carton Tap
- Leaflet Vacuum
- Product Divert
- Blister Gate Open

Other is as -

Carton Pick - The Carton Pick Vacuum Solenoid is energized in the angle band defined from START to END.

Carton Reject - The Carton Reject Solenoid is energized in the angle band defined from START to END. This Solenoid operates only if the Blister Quantity is less or Booklet not dropped for the particular Carton underneath.

Leaflet Vacuum - Vacuum will be on for a new leaflet to be pulled inside the GUK unit. This vacuum will remain on between the Start and End angles mentioned in this setting.

Next option gives second screen of PNEUMATIC SOLENOID ANGLE 2 as -

PRODUCT DIVERT - The product divert solenoid is energized the angle band defined from START to END.

BLISTER GATE OPEN - Blister Gate closes along with starting of the blister drop action & opens at this angle.

BOOKLET RELEASE - This count will help booklet to dispense out from the Booklet Dispensing Unit.

LEAFLET BAR CODE PARAMETERS SCREEN

FRONT BARCODE CHECK BAND - Booklet Front Barcode Reader Gate (Trigger) is provided in this angle band defined from START to END. Output of Reader is checked at the end of this Angle band.

LEAFLET PICK TO FRONT BARCODE READER - This is the number of Machine Cycles in which a Leaflet sucked in GUK unit, reaches below Booklet Front Barcode Reader.

FRONT BARCODE READER TO REJ. - This is number of Machine Cycles in which a Booklet (in a Carton) under Booklet Front Barcode Reader, reaches under the Reject cylinder on Push-out Conveyor.

REAR BARCODE CHECK BAND - Booklet Rear Barcode Reader Gate (Trigger) is provided in this



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Cartonator Machine (Model: WKH-100)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

angle band defined from START to END. Output of Reader is checked at the end of this Angle band.

LEAFLET PICK TO REAR BARCODE READER - This is the number of Machine Cycles in which a leaflet sucked in GUK unit, reaches below Booklet Rear Barcode Reader.

REAR BARCODE READER TO REJ. - This is number of Machine Cycles in which a Booklet (in a Carton) under Booklet Rear Barcode Reader, reaches under the Reject cylinder on Push-out Conveyor.

CARTON BAR CODE PARAMETERS SCREEN

Carton Barcode Check Band - Carton Barcode Reader Gate (Trigger) is provided in this angle band defined from START to END. Output of Reader is checked at the end of this Angle band.

Carton Drop to Barcode Reader - This is the number of Machine Cycles in which a Booklet sucked in GUK unit, reaches below Carton Barcode Reader.

Carton Barcode Reader to Reject - This is number of Machine Cycles in which a Booklet (in a Carton) under Carton Barcode Reader, reaches under the Reject cylinder on Push-out Conveyor.

BOOKLET BAR CODE PARAMETERS SCREEN

BARCODE CHECK BAND - Booklet Barcode Reader Gate (Trigger) is provided in this angle band defined from START to END. Output of Reader is checked at the end of this angle band.

BOOKLET SUCTION TO BCR - These are the counts from Booklet suction to Bar code reader sensor.

BARCODE READER TO REJECT - This is number of Machine Cycles in which a Booklet (in a Carton) under Carton Barcode Reader, reaches under the Reject cylinder on Push-out Conveyor.

5.2.6.1 All these parameters govern the functioning of sensors.

5.2.7 Set Continuous Rejection Parameters Screen (There are two different screen as per respective machine): one screen is as -

For Bad Product Quantity

- For No Leaflet Drop
- For Faulty Leaflet Front Barcode
- For Faulty Leaflet Rear Barcode
- For Faulty Carton Barcode

Second screen is as -

FOR BAD PRODUCT QUANTITY - The Carton is tripped if continuous less Blister Quantity is sensed for a programmed No. Of Cycles.

FOR NO LEAFLET DROP - The Cartonator is tripped if continuous Leaflet drop missing is sensed for a programmed No. Of Cycles.



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Cartonator Machine (Model: WKH-100)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

FOR NO BOOKLET RELEASED - These will allow the machine to run till the count reaches. Normal count is 5 and will allow the machine to run 5 cycles even booklet release does not take place.

FOR FAULTY LEAFLET FRONT BAR CODE - The Cartonator is tripped if continuous Faulty Leaflet Front Barcode is sensed for a programmed No. of Cycles.

FOR FAULTY LEAFLET REAR BAR CODE - The Cartonator is tripped if continuous Faulty Leaflet Rear Barcode is sensed for a programmed No. of Cycles. **FOR FAULTY CARTON BAR CODE** - The Cartonator is tripped if continuous Faulty Carton Barcode is sensed for a programmed No. of Cycles.

SERVO SPEED SELECTION SCREEN (If applicable) -

For 1-to-10 Blisters: This is the frequency of Operation for Blister Servo during Blister dropping cycle when parameter 'No. Of Blisters' is set from 1 to 10. This is a Factory setting.

OPERATOR CONTROL-1

OPERATOR CONTROL-2

OPERATOR CONTROL-3

5.2.7.1 In Continuous Rejection Parameters the machine will automatically stops after Rejecting same number of quantity which is entered in HMI.

5.2.7.2 For faulty leaflet/booklet front/rear bar code the carton will be rejected by the rejector.

5.2.7.3 Pharmacode scanning of cartons will be done after the auto cartonator packing

5.2.8 Manual Functions (Are used during initial setup of machine, There are two different screen as per machine) :

The first screen is as -

- Vacuum ON / OFF
- Blister servo ON / OFF
- Blister accelerator ON / OFF
- Blister Gate ON / OFF
- Air Blow ON / OFF
- Leaf let Pick ON / OFF
- Carton Pick ON / OFF
- Carton Vacuum Break ON / OFF
- Carton Reject ON / OFF
- Conveyor Motor ON / OFF
- Carton Rotary actuator ON / OFF
- Carton Tap ON / OFF
- Product Divert ON / OFF
- Divert Cylinder ON / OFF

Second screen is as -

VACCUM ON/OFF - For switching On/Off the vacuum pump in the manual mode **BLISTER SERVO**



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Cartonator Machine (Model: WKH-100)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

ON/OFF - For Switching On/Off the Blister Servo Motor in the Manual Mode.

BLISTER ACCEL. ON/OFF - For Switching On/Off the Blister Accelerator Motor in the Manual Mode

BLISTER GATE ON/OFF - For Switching On/Off the Blister Gate in Manual Mode **AIR BLOW**

ON/OFF - For Switching On/Off the Air Blow in Manual Mode **LEAFLET PICK ON/OFF** - For Switching On/Off the Leaflet Pick Solenoid in the Manual Mode

CARTON PICK ON/OFF - For Switching On/Off the Carton Pick Solenoid in Manual Mode

CARTON VACCUM BREAK ON/OFF - For Switching On/Off the Carton Vacuum Break Solenoid in Manual Mode

CARTON REJECT ON/OFF - For Switching On/Off the Carton Reject Solenoid in Manual Mode

Conveyor Motor ON/OFF- For switching the Conveyor Motor On/Off in Manual Mode

Booklet Release ON/OFF - BOOKLET will be released through the booklet dispensing unit.

PRODUCT Vacuum ON/OFF - For Switching On/Off the Product Divert in the Manual Mode.

DIVERT Cycle ON/OFF - For Switching On/Off the Divert Cylinder in the Manual Mode.

5.2.9 Manual Functions are used during initial setup of machine, during manual mode the ON button works as jog mode and machine will run till the button is pressed. manually.

5.2.10 Set the carton chain is to transport the open carton, setting two front side chain and a rear chain and middle carton chain is movable and has to be adjusted to suite the carton size.

5.2.11 Set Carton Feeder for following function

- To pick the carton out of the magazine
- To pre-open the carton
- To fully open the carton over erector bars
- To feed the carton from the top into the carton chain
- To fix the opened carton in the carton with a hold down device

5.2.12 Set the product conveyor and product Loader system. The product loader takes the blister stack over from the product chain and feeds the products along with the leaflet into the open carton.

5.2.13 Set the carton closing system: the main components of the carton closing station are:

1. Left and right side flap tucker
2. Carton lateral guides
3. Folding and closing system

5.3 **PRODUCTION DATA SCREEN:**

5.3.1 **DIAGNOSTICS:** Display diagnostic screen.



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Cartonator Machine (Model: WKH-100)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

5.3.2 MENU: Displays SELECT MENU screen.

5.3.3 This screen provide the current running data.

5.4 **CARTON MAGAZINE:**

5.4.1 This unit stores the cartons.

5.4.2 Set the carton magazine according to the length and width of the carton.

5.4.3 Load the cartons manually vertically in to the carton magazine.

5.4.4 The carton should be stored in a magazine in such a way that the cover flap is always toward the topside of the product loader.

5.4.5 The cartons come down to carton support assembly (with flap open) and transfer to the carton chain finger and pushed by pre-pusher arm.

5.5 **BOOKLET MAGAZINE:**

5.5.1 This unit stores the Booklet.

5.5.2 Set the booklet magazine according to the length and width of the booklet.

5.5.3 Load the booklet manually vertically in to the booklet magazine.

5.5.4 The booklet should be stored in a magazine in such a way that the pharmacode is always toward the topside of the product loader.

5.5.5 The booklet come down to booklet support assembly and transfer to the product finger and pushed by pusher.

5.5.6 The booklet assembly consist following separate panel -

Where



switch, "ON" of "OFF" the machine.



Start the feeder.



Stop the feeder.



STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Cleaning and Operation of Cartonator Machine (Model: WKH-100)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:



Reset the fault of the machine.



“P” for navigation in the menu. Incrementing or decrementing the value or switching over other setting option. Saving changed parameter value press “S” key.

The different parameter to be set are -

Velocity (In m/min)- Set the feed rate of the feeder.

Pieces - Setting the final value of unit counter. The feeder stop automatically when the set quantity is reached.

Over travel - It serves for the specific positioning of the product with regard to the product light barrier.

Prod. Length - Setting the product length in cm. (setting “0” means the length monitoring is deactivated)

Start Delay - Set the time spend for start the machine.

Feed Length - The distance between the front edge of the product to the front edge of the following product. (It should be less than the prod. Value).

5.8 **CARTON CHAIN AND PUSHER:**

5.8.1 Carton chain finger holds and carries the carton while it gets opened, filled by manually and closed.

5.8.2 Set the width of carton holder finger in carton chain as per the length and width of carton.

5.8.3 Set the height of top support guide as per the height of carton.

5.8.4 Set the adjustable side wall as per the height of the carton.

5.8.5 Set the side wise position of flap opener finger by loosening the clamping screw of finger and the top most position adjustment by sprocket angular position.

5.8.6 Check the correct position by rotating the machine by hand wheel. The finger should open.

5.9 **LEAFLET AND PUSHER SETTING:**

5.9.1 Set the leaflet magazine as per the length and width of leaflet.

5.9.2 Place the pre folded leaflet on the guide track by INCHING and keep the starting portion of leaflet in front of the sensor, it shows green and orange light blinking.

5.9.3 Move the leaflet towards end portion and set required folding pattern (By opening the plate and set the gap by manual method, after setting fit the plate in slot of the machine)



STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Cleaning and Operation of Cartonator Machine (Model: WKH-100)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

5.9.4 For leaflet pusher setting, loosen the side clamps and run the machine in INCH mode and check the pushing of leaflet correctly in the carton by the leaflet pusher. After setting tighten the side clamps.

5.10 Blister Feeding and Pusher setting:

5.10.1 Switch on the linking conveyor belt and set guide for blister so that blister can convey on belt properly.

5.10.2 Blister diverter is available for diverting of blister either for manually packing or for Cartonator packing. Use as per feasibility of product

5.10.3 The inter relation of the blister stack height, the separation discs and transport lugs for the blister stacks.

5.10.4 The size of the blister magazine can be changed by two digital position indicators one for longitudinal adjustment (in the direction of the travel of product chain) and the other for transversal adjustment.

5.10.5 The blister counting system counts the required blister quantity with a stepper motor into the product chain.

5.10.6 The counting system is divided into two planes.

5.10.7 The upper wheel system feeds the blister into the lower plane and from this intermediate store the blister are fed in the product chain.

5.10.8 The separations of the blister are done by separation disks.

5.11 Printing setting (Embossing/Stereo):

5.11.1 The embossing station is designed for a reverse-side tuck in closing system. Main roller of the embossing system are

- The embossing roller
- The counter for the embossing roller

5.11.2 In this station, a code is embossed on the carton flap from the bottom while passing the back pressure roll and the embossing roll.

5.11.3 The embossing letters are arranged radically.

5.11.4 For stereo printing – Remove embossing die and affix coding die on machine

5.11.5 Use coding ink for printing purpose, if required.

5.12 Camera setting for Camera 1 (front camera for leaflet):

5.12.1 Operation

5.12.1.1 Turn on the power supply and UPS supply given to the Jekson camera system.

5.12.1.2 After power on UPS become steady then turn on the controller.

5.12.1.3 Wait for 180 seconds until the countdown goes zero (Countdown on display).

5.12.1.4 Login into BPO (Jekson Code Reader) with particular user and its password screen will display as follow:



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Cartonator Machine (Model: WKH-100)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

5.12.1.5 Three different user has different rights assignment as mentioned below:

S.No.	Type of Functions	User Rights Assignment(Y/N)		
		Operator	Supervisor	Admin (Production Head)
1.	RUN/STOP machine	Y	Y	Y
2.	Parameters Setting	N	Y	Y
3.	Change Password	N	N	Y

5.12.1.6 Then start the cartonator machine which will pick the leaflet automatically and pass the leaflet under inspection camera and camera will grab the image by clicking on In Loop.

5.12.1.7 When image will come in center then user have to teach Pharmacode.

5.12.1.8 Give the ROI for Pharmacode and select option **Pharmacode**.

On clicking on pharmacode following option will appear -

Barcode

Pharmacode

OCR

LOGO

If the image is dark or light user can change the camera setting from '**DIGITIZER**' increase or decrease the shutter, brightness as per requirement.

Two different screen may appear for setting as -

Shutter: To set the CCD's exposure time.

Gain: To specify the digital (software) amplification of CCD's output. The amplification may lead to a noisy image.

Brightness: Adjust image brightness.

Packet Size: To set the 1500 value fixed.

Packet Delay: To set the 0 value (For Single Camera Application).

Frame Delay: To set the 0 value (For Single Camera Application).

For Multiple cameras, these three above settings calculate from below equation.

RGB (Red, Green, Blue): Used for white balancing.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Cleaning and Operation of Cartonator Machine (Model: WKH-100)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

Button setting

Grab: Grab a new image which reflects the changes of digitizer settings.

Default: Restore all settings to factory defaults.

Apply Changes: To commit new settings to database.

Correct Distortion: Enable this option for correcting lens barrel distortion. Select Lens from drop down list box and Select Distance between object and camera lens from drop down list box.

Custom Image: Select to enable the camera capture ROI size image rather than the whole image. In case of multiple blocks it calculates optimum ROI size (Minimum (left, top) and Maximum (right, bottom)). This basically increases the frame per second of the camera.

5.12.1.9 After selecting Pharmacode below screen will open:

Value: It displays the decoded values of Pharmacode.

Code Value: Check this option to cross verify Pharmacode decoded value with user defined value (if known). By default this option is check off.

PM Speed: It is the speed of searching object within outer ROI during inspection. Lower the speed more the accuracy of searching but results in increase of inspection time. The default value is MEDIUM.

[Note: If inspection time is more then, decreasing the size of outer ROI will be more preferable than increasing its speed.]

Search Accuracy: Percentage of template pattern found to be treated as accepted.

Extended Search Area: For checking extra bars OR lines in Pharmacode during inspection this option needs to be ON which will increase size of inner ROI (Twice of max. bar width on both sides) during inspection.

Orientation: it represents about the Orientation of bars with respect to horizontal axis.

Orientation can be horizontal (PICKET), vertical (LADDER) or Omni directional (ANY).

Direction: Standard directions like right-to-left and top-to-bottom with respect to horizontal axis. Non standard directions are also provided like left-to-right and bottom-to-top for user convenience.

Pharma Type: This is selection of type of Pharmacode as STANDARD.

Quite Zone: It is silent space on both sides of pharmacode which can be decreased if there is less spacing around pharmacode. By default it should be six times the width of barcode as specified by the "ISO standard".

Color Tolerance: It is the difference of taught color of bar and color of bar during inspection. Tolerance of bar color which should be adjusted according to the variation of light OR color of thick bar. If there is over rejection during inspection due to color variation then tolerance should be kept higher than the hint value of color tolerance shown in inspection result.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Cleaning and Operation of Cartonator Machine (Model: WKH-100)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

Contrast: This is the difference between background color and bar colors, if kept 0 then it will automatically find the value during inspection else you can fix it if there is very less difference between foreground and background so that proper value can be decoded.

Bar Angle Difference: This is the angle between the two bars within pharmacode. It is useful when pharmacode is manually or naturally distorted.

Check Standard: If it is ON then pharmacode standards of printing will be checked during inspection.

Ratio of thin and thick bars is OK or not.

Gap standards are OK or not.

Color bar width is OK or not.

Height Percent: This parameter is used for rejecting Pharmacode in case of an extra bar (small) or variable height of bars within Pharmacode is found during inspection. If you want to reject even a extra bar of small size, then its value should be kept higher (75 – 80 %). If there is over rejection during inspection due to height percent then tolerance should be kept lower than the hint value of height percent as shown in the inspection result.

5.12.1.10 After selecting all above mentioned parameter **DECODE** the pharmacode value and **SAVE** it.

5.13 **Camera setting for Camera 2 (Back camera for leaflet) (If applicable):**

5.13.1 For setting of camera 2 press on the second screen displayed on camera display.

5.13.2 Follow same procedure for the setting of camera from step no. 5.12.1.6 to 5.12.1.10.

5.14 **Camera setting for Camera 3 (Pharmacode Scanning for carton):**

5.14.1 For setting of camera 3 press on the third screen displayed on camera display.

5.14.2 Then start the cartonator machine which will pick the carton automatically and pass the carton under camera and camera will grab the image.

5.14.3 Follow same procedure for the setting of camera from step no. 5.12.1.6 to 5.12.1.10.

5.15 **Camera setting for Camera 4 (Pharmacode Scanning for booklet) (If applicable):**

5.15.1 For setting of camera 3 press on the third screen displayed on camera display.

5.15.2 Then start the cartonator machine which will pick the carton automatically and pass the carton under camera and camera will grab the image.

5.15.3 Follow same procedure for the setting of camera from step no. 5.12.1.6 to 5.12.1.10.

5.15.4 User will create a New Model and give name from **SAVE** and **RUN** option as per below screen attached:



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Cleaning and Operation of Cartonator Machine (Model: WKH-100)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:



5.15.5 After giving model name enter the Batch number and start inspection.



5.16 **Challenge test of camera for Pharmacode of leaflet/ Booklet:**

5.16.1 On addition or merging in the Pharmacode of leaflet/ Booklet the camera system must reject the particular leaflet. Record the activity in annexure –I “Challenge test for camera and cartonator”.

5.17 **Challenge test of camera for Pharmacode of carton:**

5.17.1 On addition or merging in the Pharmacode of carton the camera system must reject the particular carton. Record the activity in annexure –I “Challenge test for camera and cartonator”.

5.18 **Challenge test for CARTONATOR:**

5.18.1 **Product sensor challenge test:** Check the higher fill quantity of blisters, by placing one additional blister on the blister stack, the machine should generate alarm\stop in this case, stop the machine remove the faulty blister stack. Check for the lower fill quantity, by removing one blister from blister stack, machine should stop in this case.

5.18.2 **No carton challenge test:** Press the carton stack placed at the carton loading assembly which will not allow the pickup assembly of the carton to pick the carton leading to generation of no carton against the ok blister stack, machine should give alarm, stop the machine and remove the blisters.

5.18.3 **No leaflet/ booklet challenge test:** Stop the machine remove the folded leaflet from the conveying belt, during the insertion machine should generate alarm for no leaflet and blister will be filled in the carton and carton will be rejected at the rejection point.

Record the activity in annexure-I

Frequency: Start of the batch, after every 4 hours, after major maintenance work, every start up, at the end of the batch.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Cleaning and Operation of Cartonator Machine (Model: WKH-100)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

5.19 OPERATION

- 5.19.1 Replace the 'CLEANED' status label with 'EQUIPMENT STATUS' status label.
- 5.19.2 Record the Operation start time in the Equipment usage log sheet as per SOP "Making entries in equipment usage and cleaning log sheet".
- 5.19.3 Set the speed of the machine by pressing SET SPEED option.
- 5.19.4 After setting of all the require machine parameter switch over the machine to RUN MODE to start the machine.
- 5.19.5 After completion of batch switch off the machine by pushing the "Machine OFF" push button.
- 5.19.6 Record the operation end time in the equipment usage log as per SOP "Making entries in equipment usage and cleaning log sheet".
- 5.19.7 Replace the "EQUIPMENT STATUS" label with "UNDER CLEANING" label.
- 5.19.8 Link Conveyor belt is to be start during operation for convey the blister from blister pack machine to Cartonator and adjust speed as required by speed regulator.
- 5.19.9 During manual packing only Link conveyor belt diversion mechanism is to be used. (As applicable).

5.20 PRECAUTIONS:

- 5.20.1 For machine operation the compressed air pressure should not be less than 6 kg/cm².
- 5.20.2 Do not operate the machine without proper earthing.
- 5.20.3 During operation of the machine, if any carton/blister/leaflet etc.; gets stuck in cam proper assurance of cleaning shall be done by operator that before operation no any traces of lubricating oil/ grease are present on the cam/ cartonator bed (on which carton travels).
- 5.20.4 During machine setting ensure that carton closing assembly is not damaging the carton and carton assembly shall not be loose.

6.0 ABBREVIATION (S):

- 6.1 HMI : Human Machine interface
- 6.2 PLC : Programmable Logical control
- 6.3 SOP : Standard operating procedure
- 6.4 MMI : Man machine interface

7.0 REFERENCE (S):

- 7.1 SOP: Status labeling.
- 7.2 SOP: Making entries in equipment usage and cleaning log sheet.

8.0 ANNEXURE (S):



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Cleaning and Operation of Cartonator Machine (Model: WKH-100)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

Annexure no.	Title of Annexure	Format No.	Mode of Execution
Annexure-I	Challenge test for Camera and Cartonator		Controlled Copy

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 (05)

10.0 REVISION HISTORY:

S.No.	Version No.	Change Control No.	Reason (s) for Revision	Details of Revision	Effective Date
1.	00		New SOP	NA	

