



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Leaflet folding machine with Bar Code Reader	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down a procedure for cleaning & operation of leaflet folding machine with Bar-Code Reader.

2.0 SCOPE:

This procedure is applicable for cleaning & operation of leaflet folding machine with Bar-Code Reader in tablet production department at Macleods pharmaceutical Ltd., Nalagarh (Block N2).

3.0 RESPONSIBILITY:

Operator : Cleaning and Operation
Production Officer / Executive : Checking Cleaning And Operation
Head Production : SOP Compliance
IPQA Person : Line Clearance

4.0 DEFINITION (S):

NA

5.0 PROCEDURE:

5.1 CLEANING:

- 5.1.1 Ensure that all the materials (leaflets) of previous batch are removed from the machine.
- 5.1.2 Affix "TO BE CLEANED" label on the machine with date and sign of the production officer.
- 5.1.3 Switch off the power of machine.
- 5.1.4 Clean the machine with dry lint free cloth.
- 5.1.5 Replace the "TO BE CLEANED" status label by "CLEANED" status label on the machine with date and sign of the production officer.
- 5.1.6 Record the cleaning activity in equipment usage log as per SOP.

5.2 MACHINE SETTING:

5.2.1 FEEDING SYSTEM:

- 5.2.1.1 **Feed Tray Setting:** Papers are fed to and held in the feed tray. The feed tray can be rotated about the hinged screw to change its inclination. For smooth papers like map-litho inclination should be high.
- 5.2.1.2 **Gauge Locking Knob:** It locks the gauge to any position on feed gauge assembly mounting shaft.



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- 5.2.1.3 **Angular Setting Knob:** It is used to rotate the gauge, which is used to set the incorrect paper cuts. In such case, the paper will be pulled over one of the gauges. Rotate the gauge in the direction of pull, and tighten the star knob.
- 5.2.1.4 **Feed Gauge Adjustment Nuts:** These nuts allows to move the entire gauge assembly without disturbing the gauge settings. This adjustment helps in fine tuning creasing setting in case of cross folding operation.
- 5.2.1.5 **Setting of Pocket and Deflectors:** There are four folding pockets provided with machine. The first pocket is longer than others. All the pockets are marked with their position number. The folding pockets put in their position and turn the adjustable handle in the direction of lock to get the pocket locked. The deflector should be mounted in a similar fashion while mounting deflector. Ensure the sticker “THIS SIDE UP” in “FACE UP” condition.
- 5.2.1.6 **Paper Support Strips/ Extension Strips:** In case of lower grammage papers, support strips are used to keep leaflets straight while feeding. In case of long leaflets extension strips are used to extend the support to the leaflets at their rear and while feeding. Extension strips should be inserted through the slots provided on the rear edge of feed tray and the strip holding pockets welded at the bottom. For the narrow papers, insert one extension strip in the center slot. For wide papers, insert two extension strips.
- 5.2.1.7 **Feeder Assembly:** This roller pushes leaflets to the machine. To adjust the tension on feed roller, a spring is provided. To change the pressure, loosen the knob, move it to a suitable position in the slot and tighten it again.
NOTE: (Moving the knob closer to the feed roller will increase pressure on the paper.)
- 5.2.1.8 **Fanning Out of Paper:** leaflets should be properly fanned (shuffled) before feeding to machine. This will ensure single paper feeding.
- 5.2.1.9 **Gap Setting Roller:** This is mounted on a round shaft. This shaft is located below the feed tray.
NOTE: Gap setting roller is a fixed roller. Do not try to rotate it, it may get damaged. There are two methods of adjusting this gap.
A. Course Tuning method B. Fine Tuning Method.
- 5.2.1.9.1 **Course Tuning Method:** For setting more than 1 mm, rotate the round shaft on which the gap setting roller is mounted. Loosen the socket head screws at the left-hand side end of the swiveling bar. Rotate the bar to adjust the gap. Tighten the screws. Use the gap setting knob to fine tune the gap.
- 5.2.1.9.2 **Fine Tuning Method:** Rotate the gap setting knob provided. This will allow setting of ± 0.2 mm. When you rotate the knob clockwise, gap reduces and when you rotate it anti-clockwise gap increases. This setting should be used to fine-tune the gap.



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5.2.1.10 **Plain Stacker:** It collects the folded paper and stacks them horizontally. It has two belts which folded jobs to a collection tray, where they are accumulated. Stacker wheels are provided to arrange the paper folds one after other in an ordered way, and they should be adjusted to rest on the belts.

5.2.1.11 **Cross Folding Machine:** This machine is used, when cross folding is required with parallel folding.


5.3 SETTING OF BAR CODE READER:


5.3.1 Switch on mains of machine the Bar Code Reader starts and checks it's all commands and Head 1 and Head 2.



5.3.2 Select the set mode by moving the key to 

5.3.3 Now press F1 for main menu and it displays

Head Diagnosis		<table border="1"> <tr> <td colspan="2">Actual Code</td> <td colspan="2">ARGUS 6012</td> </tr> <tr> <td colspan="2">Visualization Code</td> <td colspan="2">S/N : 115584</td> </tr> <tr> <td colspan="2">Reference Code</td> <td colspan="2">V: 8.1.1</td> </tr> </table>				Actual Code		ARGUS 6012		Visualization Code		S/N : 115584		Reference Code		V: 8.1.1	
Actual Code						ARGUS 6012											
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Reference Code		V: 8.1.1															
Prod.Data Base																	
Protocol																	
Config.System																	
Config.ECS																	
Config.Head																	
MAIN MENU	Head 1	Head 2															
F1	F2	F3	F4	F5	F6												


Go reference code by pressing  direction key.

5.3.4 Now press F2 for head 1 setting and reset the previous bar code by pressing  at the right corner.

5.3.5 After then enter the Bar Codes by pressing the  Key for thick lines and  Key for

5.3.6 thin lines and after then press enter key

5.3.7 Now press F3 for head 2 setting and follow the step no 5.3.5 and 5.3.6

5.3.8 Now save the setting of Head 1 and head 2 by moving the key to  direction and screen displays

No evaluations available

5.3.9 Now press F1 for main menu it displays

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
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- 5.3.10 Go to head diagnosis by pressing ↓ and ↑ directional keys.
- 5.3.11 Now press F2 for head 1 and F2 for Head 2 diagnosis (i.e. for proper functioning)
- 5.3.12 After head 1 and Head 2 diagnosis go to run mode by moving the ket to  direction and now the bar code reader is ready for use.

5.3.1 OPERATION:

5.3.1.1 For Parallel Folding:

- 5.3.1.2 Put the under process label on the machine.
- 5.3.1.3 Switch on the mains of machine. The red light will glow on the panel.
- 5.3.1.4 Set the roller gaps according to the leaflet thickness.
- 5.3.1.5 Touch the  button to run the machine. Adjust the speed with speed knob 0-10.
- 5.3.1.6 Place the paper on the feed tray such that feed roller touches the center line.
- 5.3.1.7 Adjust the feed gauges along the sides of paper. Make sure that there is slight margin between one of the feed gauges and the paper. This will facilitate smooth paper flow. Adjust the angular position of gauge if required.
- 5.3.1.8 Insert the leaflet between the free wheel roller and gap setting machine in run mode.
- 5.3.1.9 If the gap setting is optimum then a slight resistance is feel while pulling the paper back.
- 5.3.1.10 Take the fanned leaflets and keep on the feed tray.
- 5.3.1.11 Keep the machine in jog forward mode and ensure that one leaflet is feed at a one time. Ensure the upper leaflet is towards the feed roller and is fed first to machine.

5.3.2 For Cross Folding:

- 5.3.2.1 After folding the paper leaflet pass over 2 and 3 plates. This process repeats for all folding pockets or deflectors.
- 5.3.2.2 Gap between the rollers is adjusted according to paper thickness.
- 5.3.2.3 Folding pockets are used to set the fold length.
- 5.3.2.4 If folding is not required the deflectors are inserted in place of folding pockets.

5.4 CHALLENGE TEST:

- 5.4.1 After setting of Pharma code reader, take a single leaflet of product, which has to be printed.
- 5.4.2 Pass that leaflet through machine, it should pass through the machine.
- 5.4.3 Now mark one or two extra lines in Pharma code.
- 5.4.4 Now again pass this leaflet with extra line through machine.



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5.4.5 The machine should get stopped.

5.4.6 This challenge test should be performed before starting folding of leaflet of any product.

6.0 ABBREVIATION (S):

IPQA : In process Quality Assurance

QA : Quality Assurance

SOP : Standard Operating Procedure

7.0 REFERENCES (S):

SOP: Making entries in equipment usage and cleaning log sheet.

SOP: Status Labeling.

8.0 ANNEXURE (S):

Nil

9.0 DISTRIBUTION:

9.1 **Master Copy** : Quality Assurance

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

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