



SOP: LFA 00076
SOP For Alu Blister Pack Machine

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1 Objective

To provide a guideline for operating the Alu blister pack machine

2 Scope

Applicable to Alu-Alu blister packing machine in production department

3 Responsibility

By Operator (execution)

By Production Pharmacist and Above (checking)

4 Accountability

Head of the Department for Production/Assigned Designee

5 Procedure

- 5.1. Check the cleanliness of the area especially of the machine. Switch the compressed air supply "on".
- 5.2. Switch the main electrical supply "on".
- 5.3. Switch the cooling unit "on".
- 5.4. Switch the Sealing Heater and set the temperature between 180°C to 200°C.
- 5.5. Set the knob switch to the starting speed.
- 5.6. Switch the electric supply "on" and press both clean button "on".
- 5.7. Check and ensure that the punching unit is clean and lubricated.
- 5.8. Attaining the operating temperature:
 - 5.8.1. Start the machine for fresh blister web.
 - 5.8.2. Stop the machine and insert aluminium foil for sealing.
 - 5.8.3. Insert a sealed web in the punching unit. Check the web tension located behind the indexing roller.
 - 5.8.4. Start the machine and adjust the idler roller of the BCP unit to get uniform overprinting.
 - 5.8.5. After the batch printing, engage the tablet-feeding unit. Open the gate for filling tablets after 2 revolutions of blister forming rollers.
- 5.9. Base Laminated Foil Change:
 - 5.9.1. Before the roll ends, stop the tablet feeding.
 - 5.9.2. Stop the machine and then reduce the speed setting.
 - 5.9.3. Disengage the idler roller to stop printing.
 - 5.9.4. To change the base laminated foil, do a lap joining.
 - 5.9.5. Start the machine with PRC.
 - 5.9.6. Switch the machine on until the joint reaches the indexing roller.

5.9.7. Insert the web into the punch while checking that the joint is outside the punch,

5.9.8. Start the tablet feeding. Once running is smooth, increase the speed.

5.10. Aluminium Foil Roll Change:

5.10.1. Switch the tablet feeding off.

5.10.2. Switch the machine and reduce the speed.

5.10.3. Switch the PRC off.

5.10.4. Stop the printing unit.

5.10.5. Measure the previous roll position and change the rolls.

5.10.6. Load the foil through the BCP unit and the sealing roller.

5.10.7. Set the PRC operation.

5.10.8. Check to make sure that the foil path is straight and even.

5.10.9. Switch the machine and PRC "on".

5.10.10. Remove the unsealed aluminium foil.

5.10.11. Check the printing operation and foil path between guide covers

5.10.12. Adjust the BCP pressure roller for the printing.

5.10.13. Start the tablet feeding and then gradually increase the speed once the operation is smooth.

5.11. Machine Stopping Procedure:

5.11.1. Switch the tablet feeding off; make sure that there are no loose tablets in the hopper.

5.11.2. Switch the machine and shut off the printing after the packed tablets are out of the machine.

5.12. Machine Shut Down Procedure (follow the guide as per 5.11):

5.12.1. Switch the electronic off.

5.12.2. Switch the sealing heaters off.

5.12.3. Remove the dust from the tablet channel feeders.

- 5.12.4. Clean the rollers and BCP printing drum do not disassemble the drive gears.
- 5.12.5. Use a brass brush to clean the sealing roller.
- 5.12.6. Switch the compressed air supply off.
- 5.12.7. Turn the compressed air supply off.
- 5.12.8. Close the Isolator off.
- 5.12.9. Switch the Mains off.

5.13. Note:

- Check that there is water circulation before starting the machine.
- Check the cooling of the blister-forming roller.
- Do not use the sealing roller without an aluminium foil.
- Frequently remove the water that is collected in the moisture trap-per.
- Do trial runs until satisfactory stripping is observed before doing the actual packing operation.
- Documented and written line clearance should be obtained from the QA personnel before doing any blister packing or any changeover of different product to a new one.
- If on lunch or break, check that there are no tablets left in the feed channel. Any leftover can cause spoilage. To start the machine, try out several blank blisters to make sure that proper overprinting of the batch details from the Coda reel in the plain foil is observed. After, commence doing regular blistering.
- During the trial run, collect all the blisters and send out to be de-foiled immediately.

5.14. Check the blister during operation or intervals for any sign of leakage.

5.15. Once operation is done, fill out the Equipment Log Book;

6 Abbreviations

SOP Standard Operating Procedure

IPA Isopropyl Alcohol

BPR Batch Packing Record

QA Quality Assurance