



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation of Rotovac 210S blister pack machine	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Purpose: To lay down operating procedure for the operation of Rotovac 210S blister pack machine.

Scope: This procedure is applicable for

Responsibility: Production Chemist
To supervise the activity

Pre-operating Check: Check no material or residue should be there.

Equipment used: Rotovac 210S blister pack machine

Operating procedure:

1. Start on the ELCB switch.
2. Release the emergency switch. This will switch on the contact heater & pressure sealing roller heater. Set the temperature at 150°C & 180°C respectively.
3. Wait for 10 minutes for heaters to attain the temperature.
4. Press the emergency switch & pass the base film.
5. Depress the emergency switch to engage the contact heater.
6. Set the speed of the machine to the minimum.
7. Take the blister formed web & pass over the Counter-sealing roller.
8. To match the pitch of Blister forming Roller & Counting Sealing Roller, loose the knurled knob & set the loop & keep slight tension between Blister Forming Roller & Counter Sealing Roller.
9. Remove the Printing Drum from the Batch Code Printing unit & fix the stereotypes on the drums as per the pitch marks on the drum
10. Remount the drum on to the Batch Code Printing unit.
11. Pass the lidding material through the Batch Code Printing unit around the Pressure Sealing Roller.
12. Adjust the Impression Roller Knob so as to get clear printing impression on the lidding material.
13. After ensuring that the web setting is perfect, put the selector switch in RUN mode. This makes the sealing roller to come down when the machine is on.
14. Pass sealed web over web indexing plate & feed into the Punching Tool.
15. Press the web against the face of the guide plate after centering, so that the web is at right angle to the Punching Tool. In this position carefully close in the web guides till they touch the extreme blisters.
16. Adjust guides such that the web moves freely without excessive play.
17. Again insert & press the web against the guide plate & observe whether the



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Ratchet position should be advanced or retarded. The ratchet must be just behind a row of blisters.

18. Check that Indexing plate face does not touch the machine body. Also note that the slide bearings do not protrude out of its guides.

19. To adjust the forward end position loosen the stroke end setter & rotate the same in either direction to achieve the desired position of the ratchet.

20. Tighten the stroke end setter.

21. Inch the machine till the Punching Tool completely opens to its upper limit.

22. Insert the web completely under the tool & place the second row of blister against the ratchet edge.

23. Inch the machine at slow speed & observe cutting of the blanks.

24. Collect samples & observe the position of the blister with respect to the blank.

26. For final setting, adjust throw setter by either increasing or decreasing the stroke length. Also observe the centering position of blisters perpendicular to the web & adjust the web guide if necessary.

27. Inch the machine at the higher speed for satisfactory performance of the Punching & Indexing unit. Now the machine is ready for product feeding.

28. Lower the feeding unit & mount the "O" ring between feeder roller pulley & Infeed Roller pulley.

29. Set the speed of Feeding Roller to 30 RPM.

30. Adjust the hopper with respect to Bowl Dish & load the product into the hopper.

31. Switch on the machine.

32. Allow the machine to retain its speed assuming the full formation of the blister.

33. Release the product stopper. If necessary, adjust the dispensing unit In or Out till the channel grooves are in line with the formed web.

34. Take out one sample of over printed foil for the approval of the over printed matter, which must cover the impression of all stereo on the over-printing drum.

35. Check the following details

Batch number

Manufacturing date

Expiry date

Retail price

It thoroughly against the BMR

36. If all the details meet the Quality standards then only send the overprinted foil to the QA department for their approval

37. Mean while bring the bulk for packing from the inspection area bring the bulk to be packed.



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38. While brining the bulk check the following details from the label

- A Product
- B Batch number
- C manufacturing date
- D Expiry date

39. Check the empty blisters for the setting parameters like sealing, pocket centering, cutting etc.

40. Wear gloves and pour the tablets in to the hopper and ensure that the tablet are coming through channel with ease; if not set the vibrator and channel.

41. Then check the sealing roller and forming roller temperature should lie within the normal limit.

42. Check the quality of the printing and add if necessary ink and thinner and adjust the printing as in the overprinted approved foil or better than that.

43. Start the machine record the start time in BMR and collect strips/blister as per BMR and keep those for the leak-seal test.

44. If the Leak seal test passes then start the blistering.

45. Monitor the over all quality of the final strips/blister through out the blistering operation.

PRECAUTIONS:

1. Do not under any circumstance allow the temperature of the roller to exceed 250°C as it could remain irremediably damaged.
2. Check that there is no condensate water in the filter unit. If necessary drain it by opening the knob in the lower part of the filter.
3. Never apply grease on the transmission chains. If required, use any thin oil.
4. Do not allow the printing ink to get accumulated on the sealing roller. Clean it by soft bristle wire brush at the end of every shift to get better sealing quality.
5. Check the oil level in oiler, gear box & vacuum pump at regular interval.
8. Never leave the hand tools on the machine.