



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Poly Bag Sealing Machine (Make: Sepack)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a procedure for cleaning and operation of poly bag sealing machine.

2.0 SCOPE:

This procedure is applicable to the cleaning and operation of poly bag sealing machine in production area.

3.0 RESPONSIBILITY:

Technical Associate : Cleaning and Operation

Officer and Executive : Supervision of cleaning and operation

Officer and Executive IPQA : Line clearance and SOP Compliance

Head Production : SOP Compliance

DEFINITION (S):

NA

5.0 PROCEDURE:

5.1 CLEANING

- 5.1.1 Replace the "UNDER PROCESS" status label with "TO BE CLEANED" status label with date and sign of the production officer.
- 5.1.2 Record the cleaning start time in equipment usage log as per SOP No.
- 5.1.3 Remove secondary packing material, as poly bags, triple laminated aluminum bag.
- 5.1.4 Clean the poly bag sealing machine and utility cable with the help of clean lint free duster.
- 5.1.5 Replace the "TO BE CLEANED" status label by "CLEANED" status label with date and sign of the production officer / QA officer.
- 5.1.6 Cleaned machine is ideal for 72 hours, if machine is not used within 72 hours re-clean the machine before use with lint free duster dipped in 70% v/v IPA solution followed by dry lint free duster and duly sign the "CLEANED" label again.
- 5.1.7 Record the cleaning activity in equipment usage log sheet as per SOP.
- 5.1.8 After completion of operation, clean the equipment within 24 hours if not in use.

5.2 MACHINE SETTING:

- 5.2.1 Switch on the main of machine
- 5.2.2 Set the thermo state knob as per the material to be sealed.
- 5.2.3 Set the sealing time through knob for proper sealing.



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5.3 OPERATION:

- 5.3.1 Replace the “CLEANED” status label by “UNDER PROCESS” status label with date and sign of the production officer.
- 5.3.2 Enter the start time in the equipment usage log sheet as per SOP No.
- 5.3.3 Switch “ON” the main of machine.
- 5.3.4 Put the filled poly bag / triple laminated aluminum bag between the two sealing jaws.
- 5.3.5 Press the foot paddle, sealing “LED” glows and sealing get start.
- 5.3.6 Press the foot paddle until the “LED OFF” and buzzer sound comes.
- 5.3.7 Release the foot paddle.
- 5.3.8 After completion of batch switch off the main of machine and enter the completion time in the equipment usage log sheet as per SOP No.
- 5.3.9 Put the “TO BE CLEANED” label dully filled and signed with production officer.

6.0 ABBREVIATION (S):

SOP : Standard Operating Procedure

LED : Light Emitting Diode

7.0 RERERENCE (S):

SOP No.: Making entries in equipment usage and cleaning log sheet

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