



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Operation and Cleaning for Vial Sealing Machine

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
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1.0 OBJECTIVE:

To lay down a procedure for Operation and cleaning of Vial Sealing Machine.

2.0 SCOPE:

This SOP is applicable for Operation and cleaning of Vial Sealing Machine at production area of Dry Powder Injectable Section.

3.0 RESPONSIBILITY:

Officer/Executive – Production

4.0 ACCOUNTABILITY:

Head – Production

5.0 ABBREVIATIONS:

BPCR	Batch Production and Control Record
DPI	Dry Powder Injection
NMT	Not more than
IPA	Iso Propyl Alcohol
Ltd.	Limited
LAF	Laminar Air Flow
MCB	Miniature Circuit Breaker
No.	Number
QA	Quality Assurance
SOP	Standard Operating Procedure
WFI	Water for Injection

6.0 PROCEDURE:

6.1 PRECAUTIONS:

- 6.1.1 Production personnel will manage for greasing & oiling of all moving parts of machine.
- 6.1.2 Production personnel will check & ensure the performance of all the sensors routinely.
- 6.1.3 Production personnel will check & ensure that all guards are at its place.
- 6.1.4 Carry out the preventive maintenance of the machine as per regular schedule.
- 6.1.5 Do not operate the machine without trained personnel.
- 6.1.6 Do not perform any maintenance during operation or when the machine is running.
- 6.1.7 In case of emergency use Red 'Twist to Open' button to stop the machine.



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6.2 OPERATION:

- 6.2.1 Check the pre start activities like LAF must be “ON”, cleanliness of area, proper aseptic gowning, environmental condition, availability of filled vials and appropriate changeover part of machine.
- 6.2.2 Assemble the sealing machine parts in aseptic condition. Wipe the gloved hands intermittently using 70% IPA during assembling.
- 6.2.3 Temperature of sealing area NMT 25°C.
- 6.2.4 Relative Humidity of sealing area is NMT 30%.
- 6.2.5 Assemble the hopper & chute at appropriate place.
- 6.2.6 Place aseptically the sterilized Flip of Seal in hopper.
- 6.2.7 Adjust the height of chute as per vial by rotating the knob and inlet and outlet star wheel.
- 6.2.8 Adjust the dispensing of seal from chute by rotating the screw of seal dispenser.
- 6.2.9 Switch “ON” the machine by MCB.
- 6.2.10 Push the start button of conveyor.
- 6.2.11 Push the start button of Vibrator.
- 6.2.12 Push the start button of main drive.
- 6.2.13 Adjust the sealing performance by using inching button.
- 6.2.14 Adjust the speed by synchronizing all the speed knob of conveyor and vibrator.
- 6.2.15 Push the button of counter to reset the counter before starting the sealing of batch.
- 6.2.16 Check the quality of sealing by observing the sealed vials. If sealing is satisfactory continue the operation. In case of improper sealing, adjust the machine for proper sealing.
- 6.2.17 After sealing is over push the stop button of main drive, vibrator and conveyor.
- 6.2.18 Switch “OFF” the machine by MCB.
- 6.2.19 Record the operation details as per “**Machine Utilization Record**” in SOP Titled “**Machine Utilization Record**”.

6.3 CLEANING:

- 6.3.1 Switch “OFF” the machine by MCB.
- 6.3.2 Collect the broken vials, seals from the floor and put them in aseptic area waste bin and send them for destruction.



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- 6.3.3** Remove any broken vials from the machine. Wipe the machine surface with WFI followed by 70% IPA.
- 6.3.4** Collect all the unused seals from Hopper and chute and send them for destruction.
- 6.3.5** Dismantle the Sealing Hopper and Chute.
- 6.3.6** Transfer both parts to washing area through the pass box for cleaning and sterilization.
- 6.3.7 Hopper and Chute Cleaning and Sterilization Procedure:**
- 6.3.7.1** Rinses dismantle Hopper and Chute using purified water thoroughly.
- 6.3.7.2** Apply 0.1% non-ionic SLS soap solution on all parts and clean it by using nylon scrubber.
- 6.3.7.3** Wash all the dismantled parts thoroughly with purified water thrice.
- 6.3.7.4** Finally rinse all the dismantled parts with filtered WFI.
- 6.3.7.5** Allow it to air dry under LAF and sterilize it at 121.4°C for 30 minutes in standard cycle of load machine parts & accessories and record the details in respective products BPCR.
- 6.3.8** Wipe the machine surface and conveyor using lint free mopping pad dipped in WFI and dry it with dry lint free mopping pad.
- 6.3.9** “Wipe Off” the whole machine surface, conveyor belt and panel using lint free mopping pad dipped in 70% IPA solution, allow it to air dry.
- 6.3.10** Clean the surrounding area of the machine with scheduled disinfectant by using 3 bucket trolley as per SOP Titled “**Cleaning and Sanitization of Sterile, Vial Washing, Ampoule Washing Area, Ampoule Hold Room, Manufacturing Area and Unit Preparation Area**”.
- 6.3.11** If machine is not used within 24 hours after cleaning re-clean it and follow step as mentioned above.
- 6.3.12** Record the cleaning details as per “**Machine Utilization Record**” in SOP Titled “**Machine Utilization Record**”.

7.0 ANNEXURES:

Not Applicable

ENCLOSERS: SOP Training Record

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance
- Controlled Copy No. 02 Production
- Master Copy Quality Assurance



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9.0 REFERENCES:

Not Applicable

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By