



## STANDARD OPERATING PROCEDURE

**Department:** Microbiology

**SOP No.:**

**Title:** Assembling, Dismantling, Handling and Storage of Port Wheels of Vials Filling Machine

**Effective Date:**

**Supersedes:** Nil

**Review Date:**

**Issue Date:**

**Page No.:**

### 1.0 Objective

To lay down a procedure for assembling, dismantling, handling and storage of port wheels of vial filling machine.

### 2.0 Scopes

This SOP is applicable for the assembling, dismantling, handling and storage of port wheels of vial filling machine of aseptic area.

### 3.0 Responsibility

Handling & Storage : Technician.

Officer and Above Production : Implementation of Procedure.

### 4.0 Accountability

Production Head

### 5.0 Procedure

#### 5.1 Prestart Up

**5.1.1** Ensure the sterilization of Teflon plate for the storage of port wheel along with the machine part.

**5.1.2** Ensure the sterilization cycle of machine part is completed.

**5.1.3** Ensure the LAF and Mobile LAF are in working condition and differential pressure is within specified limits (8 to 15 mm of wc).

**5.1.4** Ensure the piston of correct size gets sterilized.

#### 5.2 Operation

**5.2.1** As the autoclaving cycle of machine part is over unload the machine part in mobile LAF.

**5.2.2** Unload the port wheel in mobile LAF on Teflon Plate. Allow the port wheel to cool.

**5.2.3** Move the Mobile LAF to the vial filling room.



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- 5.2.4** Mop the surface of the filling machine with the help of sterilized mop with freshly prepared filtered 70% IPA.
- 5.2.5** Sanitize the hand with 70% IPA solution then remove the port wheel along with Teflon plate from mobile LAF so that contact part of the wheel does not touch the hand of operating person.
- 5.2.6** Sanitize the hand with disinfectant solution and Remove the piston from mobile LAF and fix the piston in each port of the wheel.
- 5.2.7** Once both of the port wheel get ready place first port wheel in front of the assembling point of the port wheel in vial filling machine. Hold the port wheel firmly from the middle position so as contact portion of the wheel does not touch the hand.
- 5.2.8** Position the port wheel and tight it with the help of bolt using spanner similarly tight the second port wheel and place the Teflon plate in mobile LAF.
- 5.2.9** For dismantling of port wheel remove the hopper of vial filling machine then unscrew the bolt of port wheel hold the port wheel firmly so that port wheel does not fall, place the port wheel on Teflon plate.
- 5.2.10** Similarly dismantle the second wheel and place the port wheel on Teflon plate.
- 5.2.11** Remove the machine part along with the port wheel through dynamic pass box for washing in unit preparation room.
- 5.2.12** First wash the Teflon plate and place the washed Teflon plate under LAF then wash the port wheel after washing place the port wheel on Teflon plate under LAF.

**6.0 Annexure (S)**

NA

**7.0 Reference (S)**

NA



# PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

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### 8.0 Glossary

SOP : Standard Operating Procedure.

LAF : Laminar air flow.

IPA : Isopropyl Alcohol