



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Quality Assurance	<b>SOP No.:</b>
<b>Title:</b> Transfer of Materials/Equipments from & to various cleaned area	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

### 1.0 OBJECTIVE:

To lay down the procedure for transfer of materials / equipments from & to Various Cleaned area of sterile injection Section of Production department.

### 2.0 SCOPE:

This SOP shall be applicable to transfer of materials/equipments from & to Various Cleaned area in sterile injection Section of Production department.

### 3.0 RESPONSIBILITY:

- 3.1 Juniors Technicians and above of the Sterile Injection Section shall be responsible for transfer of materials/equipments from & to various cleaned area of Injection department
- 3.2 Associate Officer and above of the Sterile Injection Section shall be responsible for execution the procedure for transfer of materials / equipments from & to various cleaned area of Injection department
- 3.3 Head production / Designee Sterile Injection Section shall be responsible for implementation of this SOP.

### 4.0 ACCOUNTABILITY:

Head Production.

### 5.0 SAFETY REQUIREMENTS:

- 5.1 Avoid direct contact of UV to any body parts.
- 5.2 Handle Disinfectant carefully.
- 5.3 Do not touch Hot Surfaces / Items without protective gloves.

### 6.0 PROCEDURE:

All material / equipment to follow below mentioned route.

#### 6.1 Transfer of Materials / Equipments



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- 6.1.1 If the material or equipment is autoclavable, clean the equipment and autoclave it as per the current version of SOP, after completion of autoclave cycle unload the equipment and take it in Aseptic / manufacturing area.
- 6.1.2 For the materials or equipments which can not be sterilized by steam sterilization but can be accommodated in pass box are to be transferred as per the procedure given below:-
- 6.1.2.1 Clean thoroughly the material or the equipment with lint free cloth & do the surface disinfection by spraying 70 % 0.22  $\mu$  Filtered IPA.
- 6.1.2.2 Open the Loading side door after ensuring unloading side door is closed, and keep the material or equipment inside the pass box.
- 6.1.2.3 Keep material under pass box for not less than 30 minute under UV.
- 6.1.2.4 Open the door from unloading side and take inside the material or equipment after Disinfection.
- 6.1.2.5 Record the activity as per Annexure-I.
- 6.1.3 Bulk solution shall be prepared in the manufacturing area and filtered using sterile filters to holding area.
- 6.1.4 Sterilized filter for online filling (All other filters shall be sterilized during SIP), filling assemblies, rubber stoppers, Aluminum seals, Silicon tubes, garments, Gloves, and other accessories required for product and disinfectant preparation shall be transferred to manufacturing and filling area through steam sterilizer and dynamic pass box and mobile LAF as applicable.
- 6.1.5 Vials after decartoning and inspection shall be transferred to vial washing area through Dynamic pass box, Vials to be used for filling should be washed in vial washing machine followed by depyrogenation in depyrogenating tunnel.
- 6.1.6 In-process rejections and filtration /filling waste will be collected in SS bin /trolley. keep the material in dynamic pass box. Inform wash area operator/ officer to receive the material for further processing.
- 6.1.7 Filtration accessories shall be kept in SS bin / trolley and keep the material in dynamic pass box. Inform wash area operator/ officer to receive the material for further processing.
- 6.1.8 Filled / stoppered vials shall be transferred from filling room to vial Sealing room, after sealing it shall be transferred to optical inspection & packing area through conveyor belt.



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- 6.1.9 Machine change parts shall be transfer through pass box after disinfection & U.V Exposure of 30 min.
- 6.1.10 Garments of manufacturing area shall be washed and dry in wash room and shall be packed there, these garments will not be sterilized and shall be transferred to mfg. change room in Dacron bag.
- 6.1.11 Used dresses and gloves of filling, manufacturing area shall be collected at end of day/ end of shift/ end of activity and shall be transferred to washing room from the first change room of the respective area and brought in manufacturing area through the material air lock.
- 6.1.12 From the air lock the closed bins containing used garments shall be taken to the washing room through the corridor. Gloves will not be washed. It will be sent to scrap yard for destruction.
- 6.1.13 Used filling assemblies and machine change parts shall be collected in SS container/ trolley, Transfer it to dynamic pass box. Inform wash area operator/ officer to receive the same for further processing.
- 6.1.14 All wastes during filling activity shall be collected in SS bins/poly bags & transfer it through dynamic pass box.
- 6.1.15 Any material to be unloaded from steam sterilizer shall be carried out by using mobile LAF under LAF unit and it will be transferred to respective area.
- 6.1.16 All the sterilized material shall be transferred from sterile material receiving area to filtration / filling / Sealing room in mobile LAF only.
- 6.1.17 For maintenance activities dedicated toolbox shall be kept in each area. If any tools, lubricants, greases and calibration instruments is required to be used which has to be taken from outside, shall be taken by following step 6.1.2.1 to 6.1.2.4.
- 6.1.18 Transfer Raw Material & primary packaging material as per the current version of SOP.
- 6.1.19 Microbiological plates, air sampler & other sampling accessories shall be transfer through material air lock of manufacturing & dynamic pass box of sterile preparation room.
- 6.1.20 Instrument used for integrity, particle monitoring, and Validation / calibration accessories should be transfer through pass box only by following step 6.1.2.1 to 6.1.2.4
- 6.1.21 Documents used for recording activity should be transfer through pass box after packing it to plastic folder only by following step 6.1.2.1 to 6.1.2.4.



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### 7.0 REFERENCES:

SOP No.	Title
	Operation and Cleaning of Autoclave cum Bung Processor Chamber
	Transfer of Material From Warehouse To Production Area

### 8.0 ANNEXURES:

Not Applicable

### 9.0 ABBREVIATIONS:

Abbreviations	Full Forms
SOP	Standard Operating Procedure
No.	Number
Dept.	Department
QA	Quality Assurance
IPA	Iso Propyl Alcohol
LAF	Laminar air flow
%	Percentage
UV	Ultra Violet
SS	Stainless Steel

### 10.0 REVISION HISTORY LOG:

Revision Number	Effective Date	Details of Change	Reason for Revision
00		Not Applicable	New Introduction