



## STANDARD OPERATING PROCEDURE

<b>Department:</b> Microbiology	<b>SOP No.:</b>
<b>Title:</b> Handling of Sterile Raw Materials during Power failure	<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 a procedure for Handling of Sterile Raw Material during Power Failure.

### 2.0 Scopes:

This SOP is applicable for the Handling of Sterile Raw Material during Power Failure.

### 3.0 Responsibility:

Officer and Above Production: Implementation of Procedure.

### 4.0 Accountability:

Production Head.

### 5.0 Procedure:

#### 6.1 Prestart Up:

**6.1.1** Ensure the LAF is in working condition and differential pressure within the specified limit (8 to 15 mm of WC).

**6.1.2** Ensure the raw material containers are placed under LAF with lid closed.

**6.1.3** Ensure the temperature and humidity of the room is within the specified limit as per product requirement.

**6.1.4** Ensure during power failure the movement in the room should be limited to unavoidable type.

#### 6.2 Operation:

**6.2.1** During power failure monitor the LAF over vial filling and sealing machines in operational condition as the LAF unit is connected with UPS.

**6.2.2** Keep always the lid of the hoppers of vial filling machine in closed condition.

**6.2.3** After resumption of power connections wait for five minutes and allow the area to get stabilized and spray 70% IPA solution before start of the operation.



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**6.2.4** Start the filling operation after checking the temperature, humidity and differential pressure of aseptic area.

**6.2.5** Mop the remaining container of RM from outside with the help of lint free mop using freshly prepared 70% IPA solution (use within 72 hrs.) thoroughly.

**6.2.6** Continue the filling operation till all the batch raw material used.

**NOTE:** In case the power failure continues for half an hour then discontinue aseptic filling operation. Cleaning and sanitization of aseptic area shall be done as per SOP.

#### **7.0 Annexure (S)**

NA

#### **8.0 Reference (S)**

SOP.

#### **9.0 Glossary**

SOP : Standard Operating Procedure.

LAF : Laminar air flow.

IPA : Isopropyl Alcohol

UPS : Uninterrupted power supply.

No. : Number.