



**STANDARD OPERATING PROCEDURE**

<b>Department:</b> Quality Assurance	<b>SOP No.:</b>
<b>Title:</b> Cleaning, Leak Testing and Sterilization of Hand Gloves	<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 Cleaning, Leak testing and Sterilization of Hand Gloves.

**2.0 SCOPE:**

This SOP shall be applicable to Cleaning, Leak testing and Sterilization of Hand Gloves of sterile injection Section of Production department.

**3.0 RESPONSIBILITY:**

- 3.1 Juniors Technicians and above of the Sterile Injection Section shall be responsible for Cleaning, Leak testing and Sterilization of Hand Gloves.
- 3.2 Associate Officer and above of the sterile injection Section shall be responsible for checking Cleaning, Leak testing and Sterilization of Hand Gloves.
- 3.3 Head production / Designee of Sterile Injection Section shall be responsible for implementation of this SOP.

**4.0 ACCOUNTABILITY:**

Head Production.

**5.0 SAFETY REQUIREMENTS:**

- 5.1 Wear Protective Gloves to Handle Hot WFI.

**6.0 PROCEDURE:**

**Note:** Cleaning, leak testing and sterilization of hand gloves shall be applicable only for non-sterile gloves of the clean area.

- 6.1 Before use, the gloves shall be checked for pinholes; the gloves are filled with Purified water and gently pressed with one hand with the open end closed with the other hand. Leaking gloves shall be discarded.
- 6.2 The selected gloves shall be washed thoroughly with Purified water to remove any adhering powder & finally wash with WFI.



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- 6.3 Fold the gloves from the bottom up to 2-3 inches.
- 6.4 Packets of the paired gloves sufficient for the day's operation shall be prepared in a similar manner.
- 6.5 The packets containing the gloves shall be placed in SS sterilizing bins with lids.
- 6.6 Run Garment sterilization cycle in autoclave cum bung processor chamber as per the current version of SOP.
- 6.7 Unload the sterilized gloves from sterile side of bung processor in cool zone area, under laminar air flow.
- 6.8 Transfer the sterilized gloves in the respective change room.
- 6.9 At the end of day's operation, the used gloves shall be discarded and fresh sterilized gloves shall be taken for the next use.

#### 7.0 REFERENCES:

SOP No.	Title
	Operation and Cleaning of Autoclave cum Bung Processor Chamber

#### 8.0 ANNEXURES:

Not Applicable

#### 9.0 ABBREVIATIONS:

Abbreviations	Full Forms
SS	Stainless Steel
UV	Ultra Violet

#### 10.0 REVISION HISTORY LOG:

Revision No.	Effective Date	Details of Change	Reason for Revision
00		Not Applicable	New Introduction