



## STANDARD OPERATING PROCEDURE

**Title:** Cleaning & Operation of Long Size Hand Gloves of Filling Machine Used

<b>SOP No.:</b>		<b>Department:</b>	Production
		<b>Effective Date:</b>	
<b>Revision No.:</b>	00	<b>Revision Date:</b>	
<b>Supersede Revision No.:</b>	Nil	<b>Page No.:</b>	1 of 3

### 1.0 OBJECTIVE:

To lay down a procedure for cleaning & operation of long size Hand gloves of filling machine used in Ampoule section.

### 2.0 SCOPE:

This SOP is applicable for cleaning & operation of long size hand gloves used in Ampoule section.

### 3.0 RESPONSIBILITY:

Officer / Executive – Production.

### 4.0 ACCOUNTABILITY:

Head – Production

### 5.0 ABBREVIATIONS:

IPA	Iso Propyl Alcohol
Ltd.	Limited
No.	Number
WFI	Water for Injection
QA	Quality Assurance
SOP	Standard Operating Procedure

### 6.0 PROCEDURE:

**6.1** Ensure that the port & gloves are duly cleaned.

**6.2** Before startup of operation, it should be ensured that Gloves are tightly fitted on gloves port.

**6.3** Use the gloves during starting to end of the operation.

**6.4** Clean the gloves externally at the end of operation with WFI, after cleaning sanitize Hand gloves with schedule disinfectant & Dry it with filtered compressed air.

**6.5** Check hand gloves physically after each operation. If any damage observed, it should be replaced with new one after checking integrity of hand gloves.

**6.6** Check integrity of hand gloves by filling Purified water inside the hand gloves. If any Leakage found then replace it with new one.

**6.7** Numbering system on each Hand gloves should be as AFG/01, 02, 03, 04.....

Where,

A- Ampoule

F-Filling

G- Gloves



# PHARMA DEVILS

PRODUCTION DEPARTMENT

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**6.8** Maximum permissible Sterilization cycle is 80 cycle.

**6.9** Cleaning Frequency- Daily after end of operation.

**6.10** Sterilization Frequency- Fortnightly or at product changeover.

### 7.0 ANNEXURES:

ANNEXURE NO.	TITLE OF ANNEXURE	FORMAT NO.
Annexure-I	Cleaning & Sterilization record of Long Size Hand Gloves	

**ENCLOSURES:** SOP Training Record.

### 8.0 DISTRIBUTION:

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

### 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

