



STANDARD OPERATING PROCEDURE

Department: Microbiology

SOP No.:

Title: Procedure for Sterilization of Aseptic Area Gowning

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

1.0 OBJECTIVE:

To lay down a procedure for sterilization of aseptic area gowning.

2.0 SCOPE:

This SOP is applicable for sterilization of aseptic area gowning.

3.0 RESPONSIBILITY:

Officer / Executive - Microbiologist

4.0 ACCOUNTABILITY:

Head – QC

5.0 PROCEDURE:

5.1 Aseptic garment includes a boiler suit, headgear and booties.

5.2 Aseptic garments should not have external pockets or unnecessary tucks. Edges of the garments should be sealed and seams to be all enveloping.

5.3 Take cleaned aseptic garments which are cleaned in such a way that they do not gather contaminants, which can later be shed while working.

5.4 Fold the boiler suit's arms and legs towards outer side to halfen their length.

5.5 Fold the boiler suit's inversely and then nearby into 3 fold.

5.6 Fold booties by inversely half of it length onwards and then folding it into two fold.

5.7 Place folded boiler suits, headgear and booties in bags provided for aseptic dress.

5.8 Put such bags in an SS container.

5.9 Label the SS container with Date and Autoclave Lot No.

5.10 Place the SS container in the autoclave and operate the garments and accessories cycle HPHV-1 (121°C for 30 minutes) as per SOP.

5.11 After completion of cycle open the door of Autoclave towards aseptic side.

5.12 Unload the autoclave and place the garment in dynamic garment storage cabinet placed in Air lock-2 and switch on the HEPA filter.

6.0 REFERENCES:

Not Applicable



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

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7.0 ANNEXURES:

Not Applicable

ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance Department
- Controlled Copy No. 02 Quality Control Department
- Master Copy Quality Assurance Department

9.0 ABBREVIATIONS:

HPHV High Pressure High Vacuum
Ltd. Limited
No. Number
QC Quality Control
QA Quality Assurance
UV Ultra Violet
SS Stainless Steel
SOP Standard Operating Procedure

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Details of Changes	Reason for Change	Effective Date	Updated By