



PHARMA DEVILS
MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Microbiology

SOP No.:

Title: Washing, Sterilization and Transportation of Sterile Garments from Production area to Microbiology Lab

Effective Date:

Supersedes: Nil

Review Date:

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1.0 OBJECTIVE

1.1 To lay down the procedure for washing, sterilization and transportation of sterile garments from production area to microbiology lab.

2.0 SCOPE

2.1 This procedure is applicable for Microbiology Laboratory.

3.0 RESPONSIBILITY

3.1 Production operator is responsible for washing, assembling and sterilization of garments.

3.2 Microbiologist/lab attendant is responsible for transportation of sterile garments from production area to microbiology lab.

4.0 ACCOUNTABILITY

4.1 Head Microbiology

5.0 EHS CONSIDERATIONS

5.1 NA



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6.0 PROCEDURE

- 6.1 Garments are washed in production area by SOP.
- 6.2 Assemble the garment as one pack which contains one head gear, one piece boiler suit, one pair booties in a lint free bag.
- 6.3 Pack the assembled garments in two tyvack bags one over another to maintain double protection.
- 6.4 Load the garments in the steam sterilizer as per validated load pattern and sterilize by SOP.
- 6.5 Unload the sterilized garments in aseptic area under LAF after sterilization cycle completion.
- 6.6 Put the sterilized garment in the SS container in DPB (dynamic pass box); ensure that SS container was placed in pass box before 20 minutes for collection of sterile garment.
- 6.7 Microbiologist/lab attendant will transfer the SS container to microbiology lab from production department.
- 6.8 Open the SS container and remove one wrapping of tyvack bag and keep in MLT room static pass box.
- 6.9 Keep it for 20 minutes under UV exposure.
- 6.10 Enter the sterility testing area as per SOP.
- 6.11 Remove second wrapping of tyvack bag and transfer the garments to dynamic garment cubicle.

7.0 DEFINITIONS AND ABBREVIATIONS

- 7.1 UV - Ultra Violet
- 7.2 DPB - Dynamic Pass Box
- 7.3 MLT - Microbial Limit Test
- 7.4 SS - Stainless Steel

8.0 REFERENCE

- 8.1 NA



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9.0 ANNEXURES

9.1 Annexure I: Sterile Garments Receiving Record

10.0 DISTRIBUTION DETAILS

10.1 Controlled copy of this SOP shall be distributed to Quality Assurance, Production and Microbiology department.

11.0 REVISION HISTORY

Supersedes SOP No.	Change Control No.	Reason for revision
NA	NA	NA

