



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Handling of Sterile Garments	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a Procedure for Handling of Sterile Area Garments.

2.0 SCOPE:

This SOP is applicable for Handling of Sterile Area Garments in the Production area at

3.0 RESPONSIBILITY:

Officer/Executive – Production

4.0 ACCOUNTABILITY:

Head – Production

5.0 DEFINITIONS:

Not Applicable

6.0 PROCEDURE:

6.1 HANDLING OF USED GARMENTS:

6.1.1 At the end of shift collect the used Garments from common change room and send to washing area.

6.1.2 Wash & dry all the used garments at washing and sterilization Area using Washing Machine kept for the same at specified place inside the laundry room.

6.1.3 Record the details of garment cleaning in garment cleaning record for aseptic area as per **Annexure-I**

6.2 HANDLING OF WASHED & DRIED GARMENTS:

6.2.1 Place all the washed & dried garments on cleaned SS table.

6.2.2 First fold Head Gear, Booties and Boiler Suit individually from inner side to outer side so that inner portion is exposed rather than outer portion.

6.2.3 Fold Head Gear from bottom, Boiler suit from sleeves and bottom and booties from upper side.



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- 6.2.4 Place Head Gear and pair of Booties with Boiler Suit and fold it.
- 6.2.5 Insert folded garments in Dacron Bag provided for the purpose or wrap in butter paper.
- 6.2.6 Place such ten or twelve sets of garments in each surgical box.
- 6.2.7 Place all the SS surgical box inside the autoclave cum bung processor by opening it's door from non sterile side.
- 6.2.8 Run the cycle of autoclave as per Load pattern.
- 6.2.9 After sterilization is over open the autoclave cum bung processor from sterile side and remove the SS surgical box having sterilized garments and transfer to sterile garment storage cabinet.
- 6.2.10 Only 80 sterilization cycles are permissible for a set of Clean Room Garment, after completion of 80 cycles garments shall be destroyed.
- 6.2.11 Record the details of garment sterilization in garment sterilization record for Aseptic area as per **Annexure-I**
- 6.2.12 Record the details of garment sterilization Cycles as per **Annexure-II**.

6.3 HANDLING OF STERILIZED GARMENTS:

- 6.3.1 Open the door of sterile garment storage cabinet and ensure that UV light control limit switch is working properly. When the door of sterile garment is opened it is automatically switched 'OFF'.
- 6.3.2 Ensure that LAF is in continuous operation.
- 6.3.3 Put all the sterile garments set one by one inside the sterile garment cabinet by removing it from perforated SS surgical box, close the door of cabinet.



PHARMA DEVILS

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7.0 ABBREVIATIONS:

Ltd.	Limited
Pvt.	Private
SOP	Standard Operating Procedure
No.	Number
QA	Quality Assurance
SS	Stainless Steel

8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Garment Cleaning & Sterilization Record	
Annexure-II	Sterilization Cycle Record Of Garments	

9.0 DISTRIBUTION:

- Controlled Copy No.01 Head Production
- Master Copy Quality Assurance Department

10.0 REFERENCES:

Not Applicable

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		



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ANNEXURE-II STERILIZATION CYCLE RECORD OF GARMENTS

Department:
Garment I.D. No.:

Line:
Date of Issuance:

Date										
Cycle	1	2	3	4	5	6	7	8	9	10
Done By Sign & Date										
Date										
Cycle	11	12	13	14	15	16	17	18	19	20
Done By Sign & Date										
Date										
Cycle	21	22	23	24	25	26	27	28	29	30
Done By Sign & Date										
Date										
Cycle	31	32	33	34	35	36	37	38	39	40
Done By Sign & Date										
Date										
Cycle	41	42	43	44	45	46	47	48	49	50
Done By Sign & Date										
Date										
Cycle	51	52	53	54	55	56	57	58	59	60
Done By Sign & Date										
Date										
Cycle	61	62	63	64	65	66	67	68	69	70
Done By Sign & Date										
Date										
Done By Sign & Date	71	72	73	74	75	76	77	78	79	80

Discarded & Destroyed on: _____

Reason: _____

Sign/Date (Production)

Sign/Date (QA):