



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Management of Sterile Garment

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
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1.0 OBJECTIVE:

To lay down a procedure for management of sterile garment.

2.0 SCOPE:

The SOP is applicable for Numbering & Control System for Sterile Garments, Checking of Sterile Dress Before and After Washing, Handling of Sterile Garments at Production Area

3.0 RESPONSIBILITY:

Officer / Executive - Production

Officer / Executive - Microbiology

4.0 ACCOUNTABILITY:

Head – Production

5.0 ABBREVIATIONS:

Ltd.	Limited
No.	Number
QA	Quality Assurance
SOP	Standard Operating Procedure
G & C	Garments and Components
IPA	Isopropyl Alcohol
LAF	Laminar Air Flow
SS	Stainless Steel
UV	Ultra Violet

6.0 PROCEDURE:

6.1 PROCEDURE NUMBERING & CONTROL SYSTEM FOR STERILE GARMENTS:

- 6.1.1** All the sterile Garments shall be assigned a unique number for its easy identification and traceability.
- 6.1.2** Identification number assigned to a set of garments shall not be assigned to another set of garments.
- 6.1.3** Numbering shall be done with permanent marker only.
- 6.1.4** Numbering shall be written on specified location for garments as follows:

Type of Garment	Location of Numbering on Garment
Head Gear :	Inner side of Head Gear at back.
Boiler Suit :	Inner side on collar.



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Booties :	Inner side of both booties at top.
Upper	Inner side on back
Inner booties	Inner side of both booties at top.
Lower	Inner side of lower at top.
Cap	Inner side of Cap at back.
Bag	Outside of bag

6.1.5 Numbering system shall be done as follows:

XX/YY-NNN

Where,

XX : Department Code

YY : Year of Issuance

NNN : Serial Number

E.g. GF/25-001

Where,

GF Denotes the Production -DPI

25 Year of Issuance (Last two digit of Year)

001 Serial Number

6.1.6 Department Code:

S.No.	Department	Department Code
1.	Blow Fill Seal area(BFS)	GF

6.1.7 Issued Garment shall be recorded in **Annexure-I**.

6.1.8 One set of Secondary Garments shall be permissible for maximum 80 sterilization cycle/ as per certificate if physically found OK.

6.1.9 One set of primary Garments shall be permissible for maximum 50 sterilization cycles as per certificate if physically found OK.

6.1.10 After cleaning of garments, folding of garments shall be done under LAF.

6.1.11 During folding, garments shall be checked to focus on following defects:

- Broken button
- Missing button



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- Loose button
- Holes / torn
- Faulty Zip
- Broken stitch
- Loose sewing threads
- Stain
- Missing of tie ribbon on headgear, boiler suit & booties.
- Exposed raw edges

6.1.12 If Physical condition of Garments is not Good/ any of defect listed above found, then it shall be discarded and record the details in **Annexure-I**.

6.1.13 Details of sterilization cycle for a particular set of Garment shall be mentioned in **Annexure-II**.

6.1.14 Reason for destruction either completion of permissible sterilization cycle or type of defect shall be mentioned in **Annexure-II**.

6.2 PROCEDURE CHECKING OF STERILE DRESS BEFORE AND AFTER WASHING:

6.2.1 PRECAUTIONS:

6.2.1.1 Inspect the dress for any damage, turning or color change after every use before washing.

6.2.1.2 Take out the dress from used dress bin.

6.2.1.3 Keep separately its Booties, Headgear, Boiler suit and inner garment set (Upper, Lower, Cap & booties).

6.2.1.4 Inspect the Booties, Headgear, Boiler suit and inner garment set (Upper, Lower, Cap & booties) for its damage.

6.2.1.5 Kept a side the damage Booties, Headgear, Boiler suit and inner garment set (Upper, Lower, Cap & booties) for destruction.

6.2.1.6 Keep the good Booties, Headgear, Boiler suit and inner garment set (Upper, Lower, Cap & booties) in ready for washing bin.

6.2.1.7 Inspect the dress for its damage after washing and keep the good dress in to the Dacron bag for sterilization.

6.2.1.8 Maintained the record in the format provide for the same.

6.2.1.9 Maintained the record details as per **Annexure-V**, Titled- “Sterile Dress Checking Before and After Washing”.

6.3 PROCEDURE HANDLING OF STERILE AREA GARMENTS:

6.3.1 HANDLING OF USED GARMENTS:



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6.3.1.1 At the end of the shift collect the drum/Bin of used Garments from Return Air Lock-II and send to Garment Washing area.

6.3.1.2 Wash/clean the drum/bin, dry it and wipe the drum with 70% IPA before returning it inside the Return Air Lock-II.

6.3.1.3 Wash & dry all the used garments at unit Preparation Area using Washing Machine kept at specified place inside the Garment Washing Area.

6.3.2 HANDLING OF WASHED & DRIED GARMENTS:

6.3.2.1 Place all the washed & dried garments on cleaned SS table under LAF.

6.3.2.2 First fold Head Gear, Booties, and Boiler Suit, inner garment (Upper, Lower and cap, Inner booties) individually from inner side to outer side so that inner portion is exposed rather than outer portion.

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

6.3.2.4 Fold inner from sleeves, lower from bottom, Inner booties from upper side.

6.3.2.5 Place Head Gear and pair of Booties with Boiler Suit and fold it.

6.3.2.6 Place one set of inner garments (Upper, Lower, Cap and pair of booties) in one decron bag.

6.3.2.7 Insert folded garments in Dacron Bag provided for the purpose.

6.3.2.8 Place sets of garments in each surgical box as per validation load pattern.

6.3.2.9 Place all SS surgical box inside the autoclave (HPHV steam sterilizer) by opening its door from non-sterile side.

6.3.2.10 Run the garments sterilization cycle of autoclave (HPHV steam sterilizer) as per validated load pattern.

6.3.2.11 After sterilization is over open the autoclave (HPHV steam sterilizer) from sterile side and remove the SS surgical box having sterilized garments and transfer it to Air Lock-II (Primary Garment) and Air Lock-III (Secondary Garment).

6.3.2.12 Only 80 sterilization cycles are permissible for a set of Clean Room Secondary Garment, after completion of 80 cycles garments shall be destroyed.

6.3.2.13 Only 50 sterilization cycles are permissible for a set of Clean Room inner Garment (primary garment), after completion of 50 cycles garments shall be destroyed.

6.3.2.14 Record the Secondary garment cleaning details in “**Garment Cleaning & Sterilization Record**” as per Format shown in **Annexure-III**.



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6.3.2.15 Record the Primary garment cleaning details in “**Garment Cleaning & Sterilization Record**” as per Format shown in **Annexure-IV**.

6.3.3 HANDLING OF STERILIZED GARMENTS:

6.3.3.1 Before Open the door of garment storage cabinet ensure that UV light working properly. When the door of sterile garment is opened ensure that the UV light is switched ‘**OFF**’.

6.3.3.2 Ensure that LAF is in continuous operation.

6.3.3.3 Put all the sterile garments set one by one inside the sterile garment cabinet by removing it from perforated SS surgical box and close the door of cabinet.

6.3.3.4 Check the UV light burning hours, if burning hours is over as per its specification change the UV tube light with another new UV tube light and put the record in as per sop no.HER-014 in **Annexure- I**.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Issuance Record for Aseptic Area Garments	
Annexure-II	Sterilization Cycle Record of Primary Garments	
Annexure-II	Sterilization Cycle Record of Secondary Garments	
Annexure-III	Secondary Garment Cleaning & Sterilization Record	
Annexure-IV	Primary Garment Cleaning & Sterilization Record	
Annexure-V	Sterile Dress Checking Before and After Washing	

ENCLOSURES: SOP Training Record.

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance
- Controlled Copy No. 02 Production
- Controlled Copy No. 03 Microbiology
- Master Copy Quality Assurance

9.0 REFERENCES:

Not Applicable.



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10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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



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ANNEXURE – II STERILIZATION CYCLE RECORD OF PRIMARY GARMENTS

Block:

Department: Production

Garment I.D. No.:

Date of Issuance:

Cycle No.	1	2	3	4	5	6	7	8	9	10
Load No.										
Sign. & Date										
Cycle No.	11	12	13	14	15	16	17	18	19	20
Load No.										
Sign. & Date										
Cycle No.	21	22	23	24	25	26	27	28	29	30
Load No.										
Sign. & Date										
Cycle No.	31	32	33	34	35	36	37	38	39	40
Load No.										
Sign. & Date										
Cycle No.	41	42	43	44	45	46	47	48	49	50
Load No.										
Sign. & Date										
Cycle No.	51	52	53	54	55	56	57	58	59	60
Load No.										
Sign. & Date										
Cycle No.	61	62	63	64	65	66	67	68	69	70
Load No.										
Sign. & Date										
Cycle No.	71	72	73	74	75	76	77	78	79	80
Load No.										
Sign. & Date										
Cycle No.										
Load No.										
Sign. & Date										
Cycle No.										
Load No.										
Sign. & Date										

Discarded & Destroyed on: _____ Reason: _____

Done By
Sign & Date

Verified By
Sign & Date



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ANNEXURE – III STERILIZATION CYCLE RECORD OF SECONDARY GARMENTS

Block:

Department: Production

Garment I.D. No.:

Date of Issuance:

Cycle No.	1	2	3	4	5	6	7	8	9	10
Load No.										
Sign. & Date										
Cycle No.	11	12	13	14	15	16	17	18	19	20
Load No.										
Sign. & Date										
Cycle No.	21	22	23	24	25	26	27	28	29	30
Load No.										
Sign. & Date										
Cycle No.	31	32	33	34	35	36	37	38	39	40
Load No.										
Sign. & Date										
Cycle No.	41	42	43	44	45	46	47	48	49	50
Load No.										
Sign. & Date										
Cycle No.	51	52	53	54	55	56	57	58	59	60
Load No.										
Sign. & Date										
Cycle No.	61	62	63	64	65	66	67	68	69	70
Load No.										
Sign. & Date										
Cycle No.	71	72	73	74	75	76	77	78	79	80
Load No.										
Sign. & Date										
Cycle No.	81	82	83	84	85	86	87	88	89	90
Load No.										
Sign. & Date										
Cycle No.	91	92	93	94	95	96	97	98	99	100
Load No.										
Sign. & Date										

Discarded & Destroyed on: _____ **Reason:** _____

Done By
Sign & Date

Verified By
Sign & Date

