



PHARMA DEVILS

WAREHOUSE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Warehouse	SOP No.:
Title: Movement of Sterilized Clean Room Garments from Production area to Sterile Material Sampling Cum Dispensing Area & Storage in Dynamic Sterile Garments Storage Cabinet	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down the procedure for movement of Sterilized Clean Room Garments from production area to Sterile Material Sampling cum dispensing area & Storage in Dynamic Sterile Garments Storage Cabinet of warehouse.

2.0 SCOPE:

This SOP is applicable for movement of Sterilized Clean Room Garments from Production area to Sterile Material Sampling cum Dispensing area & Storage in Dynamic Sterile Garments Storage Cabinet of Warehouse in Injection Section.

3.0 RESPONSIBILITY:

Officer / Executive-Warehouse
Officer / Executive-Production

4.0 ACCOUNTABILITY:

Head-Warehouse
Head - Production

5.0 ABBREVIATIONS:

DGSC	Dynamic Garment Storage Cabinet
hrs	Hours
IPA	Isopropyl Alcohol
Ltd.	Limited
No.	Number
QA	Quality Assurance
SS	Stainless Steel
SOP	Standard Operating Procedure
UV	Ultra Violet

6.0 PROCEDURE:

- 6.1** Clean room garments for warehouse shall be cleaned in garment washing area of production and sterilized daily in Autoclave of production department as per specified validated load pattern.
- 6.2** SS container containing sterilized garments shall be kept in Dynamic Pass Box of entry material sterile of Three Piece/ Dry Powder Injection line.
- 6.3** Warehouse personnel shall collect the SS container containing sterilized garments from another side of dynamic pass box of entry material sterile of Three Piece / Dry Powder Injection line.
- 6.4** Record the movement of sterilized garment in the respective log book, **Annexure-I** titled as **MOVEMENT OF STERILIZED GARMENTS**.



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- 6.5** Warehouse personnel shall bring the SS container to warehouse & moping the outer surface & bottom surface of container with 5% Silvicide/ Virosil.
- 6.6** Warehouse Personnel enter in to Sterile Material Sampling cum Dispensing area as per SOP Titled “**Entry and Exit in Sterile RM Sampling cum dispensing Area**”.
- 6.7** Make Entry in “**Sterile RM Sampling cum dispensing Area Entry - Exit Record**” as per SOP.
- 6.8** Now warehouse personnel shall keep the SS container to Dynamic garment Storage Cabinet of Change Room -2 of sterile sampling cum dispensing area and keep the garments without SS container in the DGSC.
- 6.9** While keeping the garments in DGSC, he shall check and ensure that the UV light is working properly and is in ON condition.
- 6.10** While keeping the garments in DGSC, he shall check and ensure that LAF of DGSC is working properly and is in ON condition.
- 6.11** After keeping the garments ware house personal shall enter into AL-3 and then enter into sampling cum dispensing area.
- 6.12** Now ware house personnel enter into return airlock -1 & then enter into return airlock-2 and finally exit in quarantine area.
- 6.13** After use of sterilized garment collect them into SS container and send to production area for washing and sterilization.
- 6.14** Discard the sterile garment after completion of 80 cycles of sterilization or whenever garments found torned/damage before inspection during garment washing and sterilization.
- 6.15** Use Sterile clean room garments within 48 hrs. of sterilization.
- 6.16** The above procedure shall be performed on daily basis or as per requirement while keeping garments next day, old garments shall be replaced with new sterilized garments.
- 6.17** One extra garments remains in the DGSC to transfer another lot of sterilized garments on next day in the area.
- 6.18** **OPERATION AND CLEANING OF DYNAMIC GARMENT STORAGE CABINET:**
- 6.18.1 Instructions:**
- 6.18.2** Blower & UV light of DGSC shall be kept “**ON**” always except Cleaning, Breakdown & Preventive maintenance
- 6.18.3** Switch “**OFF**” the UV lights before opening of the door to avoid the direct exposure of UV line on skin & eye.



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6.18.4 Operation:

6.18.5 Ensure that the DGSC is clean.

6.18.6 Switch “ON” the Main Switch.

6.18.7 Switch “ON” the UV Light and blower **10 minutes** before starting work.

6.18.8 Observe the reading on Magnehelic Gauge and ensure that it is between **10 to 20 mm** of water.

6.18.9 If any abnormal sound is observed from the Unit, the Unit must be checked for its wear and tear.

6.18.10 Switch “OFF” the UV light and open the door and place all the sterile set of garments inside the Dynamic Garment Storage Cabinet.

6.18.11 Close the door and ensure that even after closer of door laminar air is continuously blowing inside the garment storage cabinet and Switch “ON” the UV lights.

6.18.12 Switch “OFF” the UV lights before opening of the door.

6.18.13 If the DGSC is not working properly inform to Head Engineering by Work order for further rectification of breakdown and shall be followed the Entry, Exit & aseptic practices as per respective SOP's of area.

6.18.14 After rectification breakdown, DGSC shall be clean as define procedure and record the same in respective log of equipment's.

6.18.15 Cleaning of Dynamic Garment Storage Cabinet:

6.18.16 Switch “OFF” the laminar air flow unit of Dynamic Sterile Garment Storage Cabinet.

6.18.17 Switch “OFF” the UV light.

6.18.18 Remove any kind of Material, Particles etc. and clean the inner surface with lint free cloth or sponge.

6.18.19 Spray **70% IPA** at the inner surface of garment cabinet and inner surface of the door and wipe it with dry sponge.

6.18.20 Close the door of Dynamic Garment Storage Cabinet and mop the outside surface with **70% IPA**.



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6.18.21 Switch “ON” the electric supply for supply of laminar air flow inside the dynamic sterile garment storage cabinet and switch “ON” the UV light and let it being operation for **10 minutes.**

6.18.22 Record the cleaning details in “**Dynamic Garment Storage Cabinet Cleaning & Usage Log**” as per Format shown in **Annexure-II.**

6.18.23 Cleaning & DP monitoring Frequency: Daily once / whenever required / after Preventive maintenance activity/after rectification of breakdown.

6.18.24 Cleaning & DP monitoring Frequency: Daily once / whenever required / after Preventive maintenance activity/after rectification of breakdown.

6.19 UV BURNING RECORD FOR DYNAMIC GARMENT STORAGE CABINET:

6.19.1 Replace the UV light on **Yearly basis (± 7 days)** or due to any malfunctioning, whichever is earlier.

6.19.2 Justification of frequency as vendor recommendation is **9000hrs (365 days X 24 = 8760 hrs.)**

6.19.3 Schedule of UV replacement shall mention on yearly basis as **Annexure- VI** titled as “**Schedule of UV light replacement Record**” SOP Title **Operation and Cleaning of Dynamic Pass Boxes for Injection Section.**

6.19.4 Schedule shall be prepared by warehouse and hand over to QA for further approval.

6.19.5 UV light replacement status label shall be affix on each equipment as **Annexure-VIII** titled as “**Status Label UV light replacement**” SOP Title **Operation and Cleaning of Dynamic Pass Boxes for Injection Section**

6.19.6 Cleaning of Grill & Pre Filter:

6.19.7 Cleaning of associated filters shall be performed as per **SOP.**

6.19.8 Operation activities shall be recorded in respective log of equipment along with cleaning, preventive maintenance etc.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Movement of Sterilized Garments	



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Annexure-II	Dynamic Garment Storage Cabinet Cleaning & Usage Log”	
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ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

- Controlled copy No. 01 Quality Assurance
- Controlled copy No. 02 Warehouse
- 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



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ANNEXURE-II DYNAMIC GARMENT STORAGE CABINET CLEANING & USAGE LOG

Equipment ID:

Block:

Section:

Location:

Frequency of Cleaning & DP:

Daily once / whenever required/ after Preventive maintenance activity/after rectification of breakdown.

S.No.	Date	Activity@	Start Time	End Time	Pressure Diff. HEPA filter (10-20 mm of water)	UV Light Status (Ok/ Not Ok)	Done By	Checked By (Sign./ Date)	Remarks

Remark: @Activity means DP monitoring, Cleaning, Preventive maintenance & Breakdown related activities.

**Reviewed by QA
Sign & Date**