



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Sanitation of Aseptic/Manufacturing /Washing and Sterilization/Vial Sealing area	Effective Date:
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1.0 OBJECTIVE:

To lay down a Procedure for Cleaning and Sanitization of Aseptic/Manufacturing/Washing and sterilization/Vial sealing area.

2.0 SCOPE:

This SOP is applicable for Cleaning and Sanitation of Aseptic Area of Production at

3.0 RESPONSIBILITY:

Officer/Executive Production

4.0 ACCOUNTABILITY:

Head Production

5.0 DEFINITIONS:

5.1 Cleaning- Cleaning is the process by which clean the area by disinfectant solution on rotationally change basis to eradicate pathogenic microorganisms as well as inhibit their resistant properties.

5.2 Sanitization-Sanitization is the process by which in animate object to eradicate pathogenic microorganisms.

5.3 Aseptic-Free from contamination caused by harmful bacteria, viruses, or other microorganisms; surgically sterile or sterilized.

5.4 Sterilization-The process of making something free from bacteria or other living microorganisms.

6.0 PROCEDURE:

6.1 PRECAUTION:

6.1.1 Perform the Area Cleaning and Sanitation when there is no production activity.

6.1.2 For open equipment ensure that they are covered before cleaning and sanitization activity.

6.1.3 Handle the Disinfectants carefully to avoid contact with skin and eyes.



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- 6.1.4** Use only Validated and Approved Disinfectants. Do not use expired disinfectant solutions.
- 6.1.5** Take care to avoid disinfectant contamination with product.
- 6.1.6** Rotate the disinfectants as per frequency on Daily basis to avoid the development of Microbial Resistance.
- 6.1.7** Cleaning should start from Most Critical Area and end at Less Critical Area.
Use separate lint free mop and fresh solution for cleaning of different areas to avoid Contamination of mop and solution.

6.2 SCHEDULE OF DISINFECTANTS TO BE FOLLOWED:

6.2.1 Disinfectants shall be rotated on daily basis as per the schedule mentioned below:

1.	Actall (2.5% v/v)	A	1	5	9	13	17	21	25	29
2.	Benzalkonium chloride (0.25% v/v)	B	2	6	10	14	18	22	26	30
3.	Endomax (2.5% v/v)	C	3	7	11	15	19	23	27	31
4.	Silvicide (5.0% v/v)	D	4	8	12	16	20	24	28	-

Note: 1. After Completion of Disinfectant Cycle the same Disinfectant Cycle shall be followed for remaining month.

2. Filtered disinfectant solution shall be used in Grade B (aseptic area) and unfiltered disinfectant solution shall be used in Grade C Manufacturing/washing and Sterilization/vial sealing areas).

6.3 GENERAL CLEANING PROCEDURE TO BE FOLLOWED IN ASEPTIC MANUFACTURING /WASHING AND/VIAL SEALING AREA FOR CLEANING:

- 6.3.1** Cleaning shall be performed using Three Bucket System and should have provision to carry three buckets. Three Bucket System includes:
 - 6.3.1.1** One Bucket containing Sterile Scheduled Disinfectant.



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- 6.3.1.2 Second Bucket containing Water for Injection.
- 6.3.1.3 Third Bucket Empty.
- 6.3.2 Dip Lint Free Mop in Sterile Scheduled Disinfectant Solution.
- 6.3.3 Clean the desired area.
- 6.3.4 Squeeze the used mop in empty bucket.
- 6.3.5 Dip the mop in SS bucket containing WFI and squeeze in empty bucket.
- 6.3.6 Dip the mop in bucket containing sterile scheduled disinfectant and squeeze in empty bucket.
- 6.3.7 Clean the floor and coving with schedule disinfectant solution by using lint free mop
- 6.3.8 Clean the equipment, as per respective cleaning procedure.
- 6.3.9 Collect any solid waste (If Any) from Aseptic / Manufacturing / washing and sterilization / Vial Sealing area and pack it in Double Poly Bag, label it, and send it for destruction to scrap yard.
- 6.3.10 Clean Utility Lines, HEPA Filter Grills, Electrical Fixtures, Return Air Grill (outside), View Panels, Doors, Corners, with a lint free mop dipped in Scheduled Disinfectant Solution.
- 6.3.11 Clean and Sanitize the Drain Points as per SOP
- 6.3.12 Mop SS Cross over Bench, SS Tables & Stools and LAF Tops with Lint Free Mop dipped in Scheduled Disinfectant Solution.
- 6.3.13 After completion of cleaning activity replace the garment with fresh garment.
- 6.3.14 Record the cleaning activities in cleaning and sanitization of Aseptic Area Annexure-I.
- 6.3.15 Garment cabinet shall be cleaned once in a day with 70% IPA. In case of Filling Area Garments, open the sterile garment cabinet, remove all the garments and keep in SS sterile container and close the lid.
- 6.3.16 Before the cleaning Switch 'OFF' the sterile garment cabinet from main switch



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6.3.17 Clean the inner surface of garment cabinet followed by outer surface with lint free mop dipped in 70% IPA Solution. Switch 'ON' the garment cabinet for approximately 30 minutes for UV exposure. Transfer the garment from SS sterile container to sterile garment cabinet.

Frequency: Once in a day or whenever required.

6.3.18 Frequency of Cleaning of Accessories:

6.3.18.1 Walls above 6 Feet height, Ceiling, HEPA Filters Grills, Tube Light and Electrical Fixtures, Return Air Grill shall be cleaned weekly once.

6.3.18.2 SS Table, Crossover Bench, Doors, View Glass, Floors, SS Pallets, SOP Stands, Petri Plate Stands, SS Trolley, SS Bucket, Used Garment Collection Bin, Mirror, Status Board, Utility Lines should be cleaned daily once.

6.4 SPECIFIC CLEANING AND SANITATION PROCEDURE FOR ASEPTIC AREA/MANUFACTURING AREA/WASHING AND STERILIZATION AREA AND VIAL SEALING AREA:

6.4.1 Specific Cleaning and Sanitation Procedure For Aseptic Area:

6.4.1.1 Aseptic Area Cleaning shall be performed as per below sequence:

- Ceiling & Walls
- Outer Surface of Equipments
- Accessories
- View Glass and Doors.
- Floor

6.4.1.2 Procedure for Daily Cleaning:

6.4.1.2.1 Enter the Aseptic Area as per SOP and Ensure that NO Production Activity is in progress.

6.4.1.2.2 Take freshly prepared Disinfectant Solution scheduled for the day in one SS Bucket, Filtered WFI in second Bucket & third Bucket empty.

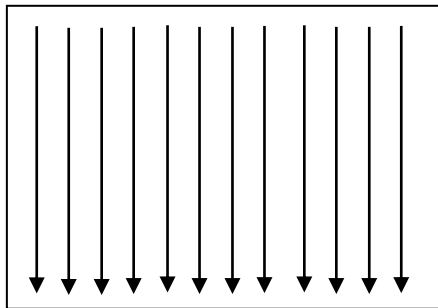


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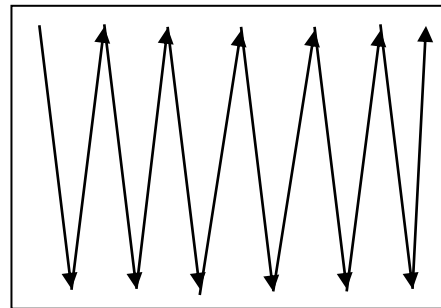
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- 6.4.1.2.3 Wipe the View Glass & Door with a lint free mop dipped in scheduled disinfectant solution.
- 6.4.1.2.4 Clean the external surface of all the Equipments.
- 6.4.1.2.5 Floor shall be cleaned in the last stage of cleaning.
- 6.4.1.2.6 After every two or three Strokes of Moping, squeeze the mop in the empty bucket.

Note:-Clean the surface in unidirectional flow with two to three strokes followed squeezing of mop as per given diagram & during cleaning mop should not be overlapped. In case of Zigzag movement again repeat the same surface with unidirectional flow followed by above procedure.



**Unidirectional Cleaning
(Proper Way of Cleaning)**



**Zigzag Cleaning
(Wrong Way of Cleaning)**

- 6.4.1.2.7 Follow the flow chart for cleaning procedure as per Annexure-II
- 6.4.1.2.8 Clean the mop in WFI kept in the second bucket.
- 6.4.1.2.9 Dip the mop in the Disinfectant Solution and continue the mopping.
- 6.4.1.2.10 Discard the used solution, WFI of all the Three Buckets and mop after Cleaning & Sanitation of One Room, and take Fresh Solution & Filtered WFI for cleaning of each room.
- 6.4.1.2.11 Repeat the above procedure for cleaning of entire Aseptic Area.
- 6.4.1.2.12 After completion of cleaning activity, person performing Cleaning shall replace the Aseptic Area Garment with fresh Aseptic Area Garment.



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Frequency: At the end of the Activity / at the end of the Shift (In Case of No Production Activity)

6.4.1.3 Procedure for Weekly Cleaning :

6.4.1.3.1 In addition to daily cleaning activity, clean the ceiling, walls with disinfectant solution as per schedule, (Walls shall be cleaned from Top to Bottom), Pressure/Temperature/RH Measuring Device, Electrical Fittings and Telephone).

6.4.1.3.2 For fixtures having electrical fitting do not spray the schedule disinfectant, just wipe with dry lint free mop.

6.4.1.3.3 In case of tube light fixtures if foreign material or dust found then switch off the tube light, open the tube light fixtures from service floor and clean it using dry clean lint free mops.

Frequency: Once in a week, at the end of the Activity/at the end of the Shift (In Case of No Production Activity).

6.4.2 Specific Cleaning and Sanitation Procedure for Manufacturing Area/Washing and sterilization and Sealing area:

6.4.2.1 Manufacturing Area /washing and sterilization area/ vial Sealing Area Cleaning shall be performed as per below sequence:

- Ceiling & Walls
- Outer Surface of Equipments
- Accessories
- View Glass and Doors
- Floor

6.4.2.2 Procedure for Daily Cleaning:

6.4.2.2.1 Enter the Manufacturing Area/washing and sterilization area/Vial Sealing Area as per **SOP.**

6.4.2.2.2 Ensure that Batch Manufacturing/washing and sterilization area/Vial Sealing Area



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Activity is not in progress.

- 6.4.2.2.3 Wipe the View Glass & Door with a lint free mop dipped in scheduled disinfectant solution.
 - 6.4.2.2.4 Floor shall be cleaned in the last stage of cleaning.
 - 6.4.2.2.5 After every two or Three Strokes of Moping, squeeze the mop in the empty bucket.
 - 6.4.2.2.6 Clean the mop in filtered WFI kept in the second bucket.
 - 6.4.2.2.7 Dip the mop in the Disinfectant Solution and continue the mopping.
 - 6.4.2.2.8 Discard the used solution and WFI of all the Three Buckets after Cleaning & Sanitation of One Room, and take Fresh Solution & Filtered WFI for cleaning of each room.
 - 6.4.2.2.9 Repeat the above procedure for cleaning of entire Manufacturing Area/washing and sterilization area/Vial Sealing Area.
 - 6.4.2.2.10 After completion of cleaning activity, person performing Cleaning shall replace the Manufacturing Area Garment / washing and sterilization area and Sealing Area.
- Frequency:** Daily & After Operation.

6.4.2.3 Procedure for Weekly Cleaning:

- 6.4.2.3.1 In addition to daily cleaning activity, clean the ceiling, walls with disinfectant solution as per schedule, (Walls shall be cleaned from Top to Bottom), Pressure/Temperature/RH Measuring Device, Electrical Fittings and Telephone).
- 6.4.2.3.2 For fixtures having electrical fitting do not spray the schedule disinfectant, just wipe with dry lint free mop.
- 6.4.2.3.3 In case of tube light fixtures if foreign material or dust found then switch off the tube light, open the tube light fixtures from service floor and clean it using dry clean lint free mops.

Frequency: Once in a week, at the end of the Activity / at the end of the Shift (In Case of No Production Activity)



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6.5 TRANSFER OF TOOLS FOR MAINTENANCE PURPOSE:

6.5.1 Tools & equipment required to carry the maintenance activity shall be carried in the Aseptic Area / Manufacturing/ washing & sterilization area and sealing area as:

6.5.1.1 A set of sterilized tools required for routine assembly shall be kept in the Aseptic Area itself.

6.5.1.2 Tools from outside (If required), shall be transferred in the Aseptic Area by sanitizing them with scheduled disinfectant followed by dry mopping using lint free mop & UV exposure in Pass Box.

6.5.1.3 Tools from outside (If required), shall be transferred in respective Area by sanitizing them with scheduled disinfectant followed by dry mopping using lint free mop & UV exposure in Pass Box.

6.6 Record manufacturing /washing & sterilization/vial sealing area in **Annexure-III**

6.7 Refer the flow chart for cleaning procedure as per **Annexure- II**

7.0 ABBREVIATIONS:

SOP	Standard Operation Procedure
WFI	Water for Injection
Ltd.	Limited
No.	Number
QA	Quality Assurance
LAF	Laminar air flow
SS	Stainless steel
HEPA	High efficiency particulate air
Pvt.	Private
UV	Ultra violet light



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8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Cleaning & Sanitation Of Filling Area	
Annexure-II	Flow Chart for Cleaning Process	
Annexure-III	Cleaning & Sanitation Record (manufacturing / washing & sterilization/vial sealing area)	

9.0 DISTRIBUTION:

- Controlled Copy No.2 Production Department
- Master Copy Quality Assurance

10.0 REFERENCES:

- SOP titled “Cleaning & Sanitization of Drain Traps in Production Area”.

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 I
CLEANING & SANITATION OF FILLING AREA

Date: _____ **Frequency:** Daily & After Operation

Area: _____ **Disinfectant Used:** _____

Time		From	To	From	To	From	To
Celling & Wall Cleaning Above 6 ft.	W						
Wall Cleaning Up To 6 ft. height	D						
Window & Glass Cleaning	D						
Door & Glass Cleaning	D						
Pallets & Furniture Cleaning	D						
Equipment Cleaning (External surface)	D						
LAF/RLAF (External surface) Except HEPA Filter	D						
Floor Cleaning & Mopping	D						
Done By Sign & Date							
Checked By							

- IF Cleaning has done please tick mark if not done put the NA



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ANNEXURE II

	FLOW CHART OF CLEANING PROCEDURE

