



SOP for Cleaning after Media Fill

1.0 OBJECTIVE:

To lay down the procedure for cleaning after media fill.

2.0 SCOPE:

This SOP shall be applicable to cleaning after media fill of sterile injection section of Production Department.

3.0 RESPONSIBILITY

- 3.1 Junior Technicians and above of the sterile injection section shall be responsible for cleaning after media fill.
- 3.2 Associate Officers and above of the sterile injection section shall be responsible for checking cleaning after media fill.
- 3.3 Head production / Designee of sterile injection section shall be responsible for implementation of this SOP.

4.0 ACCOUNTABILITY:

Head Production

5.0 SAFETY REQUIREMENTS:

- 5.1 Wear hand gloves during activity.
- 5.2 Don't touch any moving part of machine.
- 5.3 Handle the disinfectants carefully to avoid contact with skin and eyes.

6.0 PROCEDURE:

6.1 Precaution

- 6.1.1 Use only validated disinfectants.
- 6.1.2 Do not use expired disinfectant solutions.
- 6.1.3 The cleaning should start from most critical area and end at less critical area.

6.2 Procedure for cleaning

- 6.2.1 During media fill operation if any spillage of media is occurred then immediately spray the scheduled disinfectant on the spillage occurred, clean it with lint free mop followed by lint free mop dipped in scheduled disinfectant.



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- 6.2.2 At the end of the media fill operations and after completion of all microbial sampling like surface, personal swabs of all operators, officers, Dismantle & remove the following items and send to equipment washing area for cleaning.
- 6.2.2.1 Filling & Sealing assemblies / accessories.
- 6.2.2.2 S.S. Vessels containing media.
- 6.2.2.3 Left over vials, rubber stoppers and seals.
- 6.2.2.4 Filter Housing with filter.
- 6.2.2.5 Buffer Bottle & silicone tubing's.
- 6.2.3 Media fill used filling assembly's (filling and gassing needles, filling pump, Buffer bottle, S.S. valves) triclover clamps, Filter Housing with filter, scoops, spatulas, glass equipments etc shall be dismantled, cleaned with Purified Water & then rinse with WFI two times as per the current version of SOP, Sterilize all equipments in steam sterilizer, after First sterilization, rinse all the equipments with water for injection and again re sterilize the equipments.
- 6.2.4 After completion of activity, CIP of tanks (Manufacturing and Holding), millitrain & transfer line shall be done two times & after completion of CIP, SIP shall be done two times.
- 6.2.5 Mop all exposed surfaces of Vial filling & sealing machine, glass panels, HEPA filter grills, rigid barriers, trolleys, handles of doors, return risers, walls, ceilings & floor with WFI and then with scheduled disinfectant solution using lint free mop.
- 6.2.6 In all the hard to reach areas the disinfectant solution shall be sprayed with help of fogger, as per the current version of SOP.
- 6.2.7 All the mops, gloves used during media fill and cleaning should be collected in poly bag and then transferred to equipment wash area, spray scheduled disinfectant solution, close the mouth of polybag and send it for destruction to scrap area.
- 6.2.8 Silicon tubing's, filters shall be cleaned with purified water and then dip all items in scheduled disinfectant solution. Cut all tubing's, filters and pack them in polybag, Label them and send to scrap yard for destruction.
- 6.2.9 All used garments shall be removed from the area and dipped in scheduled disinfectant solution and wash separately in washing machine.
- 6.2.10 All goggles used during media shall be cleaned separately in equipment washing area and then shall be sterilized.
- 6.2.11 Left over media should be deactivated with scheduled disinfectant & drain it in to ETP.
- 6.2.12 Do the fogging of whole area with scheduled disinfectant.
- 6.2.13 Next day, allow to micro department for air sampling and plate exposure.



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7.0 REFERENCES:

SOP No.	Title
	Cleaning of Filling Machine parts
	Operation and Cleaning of Fogger

8.0 ANNEXURES:

Not Applicable

9.0 ABBREVIATIONS:

Abbreviations	Full Forms
SOP	Standard Operating Procedure
No.	Number
Dept.	Department
QA	Quality Assurance
QC	Quality Control
WFI	Water For Injection
AHU	Air Handling unit
LAF	Laminar Air Flow
HEPA	High efficiency particulate air filter
ETP	Effluent treatment plant

10.0 REVISION HISTORY LOG

Revision Number	Effective Date	Details of Change	Reason for Revision
00		Not Applicable	New Introduction