



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning & Sanitization in Aseptic Area

SOP No.:		Department:	Microbiology
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	1 of 3

1.0 Objective

To lay down a procedure for Cleaning & Sanitization in aseptic area.

2.0 Scopes

This SOP is applicable for all the persons working in aseptic area.

3.0 Responsibility

Technician : Cleaning & Sanitization.

Officer and Above Production/ IPQA Officer : Implementation of Procedure.

4.0 Accountability

Production Head

5.0 Procedure

- ◆ Cleaning of aseptic area to be performed after completion of aseptic operation with vacuum cleaner.
- ◆ Sanitization of aseptic area to be performed before start of any aseptic operation with freshly prepared & 0.22 μ filtered 70% IPA and after completion of aseptic operation.

- ◆ In aseptic area during process spillage cleaning to be done with lint free mop on vial filling and bunging machine, filling and sealing conveyors, vial sealing machine, balance and balance table and then on the floor.

6.1 Cleaning of aseptic area at intermediate breaks.

6.1.1 Cleaning of vial filling and bunging machine, vial sealing machine, conveyor of Filling and sealing machine, balance and balance table and process spillage to be done with lint free mop and to be sanitized with 70% IPA.

6.2 Cleaning of aseptic area after completion of day's operation.

6.2.1 Follow step 6.1.1 for dry cleaning.

6.2.2 For wet mopping use two pre-sterilized SS buckets filled with WFI.



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6.2.3 Dip a pre-sterilized lint free mop in one bucket, squeeze it and use for cleaning of the surfaces of machines, ceilings, walls, floors and LAF tops.

6.2.4 Then dip the same mop in other bucket for cleaning of the mop.

6.2.5 During mopping ensure unidirectional movement of the mop.

6.2.6 Sanitization before starting up of any operation to be done by spraying of filtered 70% IPA in the concerned area.

6.3 Sanitization of aseptic area after completion of aseptic operation.

6.3.1 Ensure availability of sanitizing solution as per schedule.

6.3.2 Use two pre-sterilized SS buckets, one filled with WFI and another filled with disinfectant solution.

6.3.3 Dip a pre-sterilized lint free mop in bucket filled with sanitization solution, squeeze it and use for sanitization of the surface of machines, ceiling, walls, LAFs, floors, and accessories like stools, hangers, mirrors, cross-over bench etc.

6.3.4 Then dip the same mop in the bucket filled with WFI for cleaning of the mop.

6.3.5 During mopping unidirectional movement of the mop.

6.3.6 Discard the mop, disinfectant solution and WFI after using in one area.

6.3.7 Sent the buckets outside through dynamic pass box.

6.3.8 Take fresh set of mops, disinfectant solution and WFI for a different area inside the aseptic area.

6.3.9 Sanitize the aseptic area using Fogger machine as per the sanitization schedule.

6.4 Sanitization of aseptic area during aseptic operation.

6.4.1 Use 70% filtered IPA spray for sanitization of aseptic area during aseptic operation.



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NOTE: During operation spraying to be done outside the working station and laminar air flow for sanitization.

6.4.2 For intermediate hand sanitization use freshly prepared 70% filtered IPA (use within before 72 hrs.)

7.0 Annexure (S)

Annexure-I Sanitization Schedule for Disinfectant

Annexure-II Disinfectant Solution Preparation Record for Aseptic Area.

8.0 Reference (S)

NA

9.0 Glossary

SOP : Standard Operating Procedure.

LAF : Laminar air flow.

IPA : Iso-propyl Alcohol

No : Number

SS : Stainless steel

WFI : Water for Injection