

Title: Cleaning and Sterilization of Aseptic Manufacturing Equipment				
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Cleaning and Sterilization of Aseptic Manufacturing Equipment

Introduction

This document provides guidance in the cleaning and sterilization of aseptic manufacturing equipment to minimize the risk of particulate and microbiological contamination.

1. Washing Bays for Initial Cleaning and Final Rinsing of Equipment should include, and not be limited to, the following design considerations:
 - Floors sloped to a drain;
 - A minimum two (2) inch (5cm) air break to drains;
 - Water contained and drained within the washing bay;
 - Ventilated area to minimize condensation on ceilings and walls; and
 - Utilities identified (e.g., water, filtered compressed air).

2. Equipment Washing Machines or Cabinets used to clean small pieces of equipment (e.g., beakers, clamps) should include, and not be limited to, the following design considerations:
 - Stainless steel construction, designed to drain and not retain water;
 - Effluent water sample port;
 - Stainless steel trays and/or baskets designed to be self-draining; and
 - Mechanism to remove excess moisture after washing.

3. Equipment should be cleaned promptly after use. The maximum time interval for leaving equipment in the soiled state should be specified and should not exceed fourteen (14) calendar days.

4. Equipment that will not be used or sterilized immediately should be protected from particulate and microbiological contamination and stored in a designated area with the applicable air classification. Protective measures include, but are not limited to:
 - Store small items in metal cabinets or on metal shelves; and
 - Cover large items (e.g., portable tanks) with non-shedding wraps.

5. If Not Used or Sterilized Within the Maximum Validated Time Interval between cleaning and sterilization or sterilization and use, equipment should be re-cleaned and re-sterilized.

6. Equipment should be protected from damage and should be washed in a manner that precludes generation of particles.