

## Cleaning and Sterilization of Aseptic Manufacturing Equipment

8. Selection Criteria for Wrapping Materials Used to Protect Equipment that will be steam sterilized should include, and not be limited to, the following:
  - Non-shedding material that allows adequate air removal, steam penetration, and complete drying of the wrapped equipment following sterilization;
  - Barrier to protect the equipment from microorganisms and particulates after sterilization and before use; and
  - Resistant to tearing and puncture.
9. Documentation of Equipment Sterilization should include, but not be limited to:
  - Date and time of sterilization;
  - Identification of person performing sterilization activities; and
  - Sterilization batch cycle or batch number.
10. Wrapped or Packaged Sterilized Equipment should be visually inspected for dryness and package integrity prior to being placed in an APA processing room or the APA equipment storage area. Any torn, compressed, wet, or punctured package should be labeled as damaged and removed from the APA.
11. Preventive Maintenance (PM) of CIP/SIP Systems should include, and not be limited to, the following:
  - Calibration of Instruments and Elements (I/Es);
  - Verification of cycle parameters (e.g., length of each cycle, amount of CIP chemicals used during the various cycles, pH);
  - Inspection of the CIP/SIP system for rusting, pitting, or corrosion; and Passivation, as required.