AseptiKits™
Revolutionizing Sterile Preparations

Regulatory Compliance
USP <797> and PALA Technology Products

Advanced Sterile Compounding with PALA Technology Kits

PALA is a new technology that advances and simplifies the practice of sterile compounding. PALA technology is compliant with USP Chapter <797>. As stated in section 1.1, "The use of technologies, techniques, materials, and procedures other than those described in this chapter is not prohibited as long as they are noninferior to those described herein and validated for the intended purpose." The following documentation supports using PALA technology products in a USP <797> facility.

Abbreviated Guide: White Paper: Regulatory Compliance USP Chapter <797> and PALA Technology Products

References

USP <797> Pharmaceutical Compounding - Sterile Preparations

Abbreviated Guide: White Paper: Regulatory Compliance
USP Chapter <797> and PALA Technology Products

INDEPENDENTLY VERIFIED
USP 797 COMPLIANT
CLOSED-SYSTEM 0.22 µm FILTER STERILIZATION
NONINFERIOR
ENHANCED
NEW TECHNOLOGY

PALA TECHNOLOGY

Maintain Sterility

Protect Critical Sites

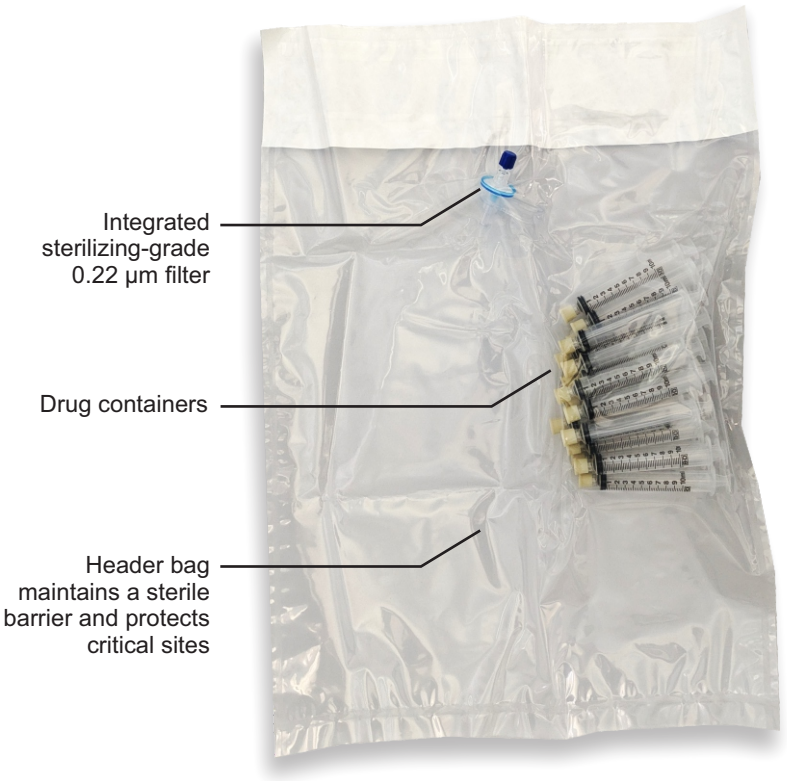
Sterile compounding without a clean room or laminar flow hood.

AseptiKits™
Revolutionizing Sterile Preparations

Sterile Compounding with PALA Technology Kits

Advanced Sterile Compounding with PALA Technology Kits

PALA technology products advance the practice of sterile compounding by reducing the primary engineering control (PEC) clean room to a single-use, terminally sterilized convenience kit. PALA technology maintains sterility (SAL 10^{-6}) equal to or better than an ISO Class 5 clean room throughout the filling process. Drug entering the kit is sterilized by an integrated 0.22 µm sterilizing-grade filter. Critical sites are protected by the kit, effectively eliminating touch contamination at these sites. Drug containers are capped and sealed before the kit is opened to maintain drug sterility.



PALA Technology Products and USP <797>:

- Meet or exceed USP <797> requirements for sterile compounding.
- Enable sterile compounding without facility-scale infrastructure such as clean rooms and laminar flow hoods.
- Eliminate human error risks associated with clean room procedures
- Enable point-of-care sterile compounding
- Improve patient access, especially in under-served areas
- Reduce medication errors through simplified procedures
- Prevent vial misuse and associated contamination risks
- Are easy to validate in your facility for Category 1, 2 and 3 CSPs

Syrikit Demo Video by
Dr. Matthew S. Ward, MD

For More Information:
website: www.aseptikits.com
email: sales@aseptikits.com
phone: 844-863-5170